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# Transcript of Nicolas Bu-Saba, M.D.

**Date:** February 21, 2025

**Case:** Neurent Medical Inc., et al. -v- The Foundry, LLC (PTAB)

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WORLDWIDE COURT REPORTING & LITIGATION TECHNOLOGY

The Foundry, LLC Exhibit 2009: IPR2024-00279  
Neurent Medical Inc. & Neurent Medical Ltd. v. The Foundry, LLC

1 UNITED STATES PATENT AND TRADEMARK OFFICE  
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD  
3 - - - - -x  
4 NEURENT MEDICAL INC. and :  
5 NEURENT MEDICAL LTD., :  
6 Petitioners, : IPR2024-00279  
7 v. : Patent 10,610,675  
8 THE FOUNDRY, LLC, :  
9 Patent Owner.  
10 - - - - -x  
11  
12 Deposition of Nicolas Bu-Saba, M.D.  
13 Boston, Massachusetts  
14 February 21, 2025  
15 9:01 a.m.  
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20 Job No.: 570097  
21 Pages: 1 - 128  
22 Reported By: Alan H. Brock, RDR, CRR

1 UNITED STATES PATENT AND TRADEMARK OFFICE  
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD  
3 - - - - -x  
4 NEURENT MEDICAL INC. and :  
5 NEURENT MEDICAL LTD., :  
6 Petitioners, : IPR2024-00280  
7 v. : Patent 10,894,011  
8 THE FOUNDRY, LLC, :  
9 Patent Owner.  
10 - - - - -x

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12 Deposition of Nicolas Bu-Saba, M.D.  
13 Boston, Massachusetts  
14 February 21, 2025  
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1 UNITED STATES PATENT AND TRADEMARK OFFICE  
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD  
3 - - - - -x  
4 NEURENT MEDICAL INC. and :  
5 NEURENT MEDICAL LTD., :  
6 Petitioners, : IPR2024-00669  
7 v. : Patent 11,679,077  
8 THE FOUNDRY, LLC, :  
9 Patent Owner.  
10 - - - - -x

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12 Deposition of Nicolas Bu-Saba, M.D.  
13 Boston, Massachusetts  
14 February 21, 2025  
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C O N T E N T S

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PREVIOUSLY MARKED EXHIBITS

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| Exhibit 1004, Levine testimony         | 83   |
| Exhibit 1005, Makower patent           | 113  |
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1 February 21, 2025 9:01 a.m.

2 P R O C E E D I N G S

3 NICOLAS BU-SABA, M.D.,

4 being first duly sworn or affirmed to testify to the  
5 truth, the whole truth, and nothing but the truth, was  
6 examined and testified as follows:

7 EXAMINATION

8 BY MR. BRIGGS:

9 Q. Good morning, Dr. Bu-Saba. It's nice to see  
10 you again.

11 A. Nice to see you again, too.

12 Q. As you may recall, my name is Heath Briggs,  
13 I'm from the law firm of Greenberg Traurig, and I  
14 represent the patent owner in this case, which is the  
15 founder. Do you understand that?

16 A. Yes.

17 Q. Could you please state your full name for the  
18 record.

19 A. Nicolas Bu-Saba, Nicolas without H, Bu-Saba  
20 B-u-S-a-b-a.

21 Q. Thank you. And you understand you're here  
22 for a deposition in connection with three proceedings

1 before the U.S. Patent and Trademark Office, called  
2 inter partes reviews?

3 A. I do.

4 Q. And for the record, those matters are known  
5 as IPR2024-00279, IPR 00280, and IPR2024-00669. Okay?

6 A. Yes.

7 Q. So have you been deposed since our last  
8 deposition, in October?

9 A. I have not.

10 Q. I know you know the ground rules, but I'm  
11 just going to go over them again so we're all on the  
12 same page. First, I'm going to be asking questions,  
13 and it's -- so the record is clear, it's important  
14 that we don't talk over each other when I'm asking  
15 questions. So what I'd appreciate is if, when I'm  
16 asking a question, you could wait for me to finish my  
17 question. And likewise, when you're answering, I'll  
18 try to wait with until you finish your answer so the  
19 record is clear. Is that okay?

20 A. That's okay.

21 Q. And let's make sure we're doing verbal  
22 answers, no nods, stuff like that. Okay?

1           A.    Okay.

2           Q.    And I will do my best to try to ask a clear  
3 question, but if you do not understand my question,  
4 could you please let me know?

5           A.    I will.

6           Q.    So what that means is, if you answer my  
7 question, I will assume you understood it.  Okay?

8           A.    Agreed.

9           Q.    As you know, from time to time counsel on  
10 behalf of Neurent may lodge an objection, and unless  
11 they tell you not to answer the question, you still  
12 have to answer the question.  Do you understand that?

13          A.    I understand.

14          Q.    And breaks -- I think we talked about this  
15 last time:  Typically we do a break about every 60  
16 minutes.  Is that okay?

17          A.    That's okay.

18          Q.    If you need to go on break more urgently,  
19 that's fine.  But if there's a pending question, I  
20 would just ask that you finish the answer to that  
21 question before we go on break.  Okay?

22          A.    Okay.

1 Q. And you obviously just were sworn in, so you  
2 understand you're required to testify truthfully  
3 today?

4 A. I do.

5 Q. Is there any reason you cannot testify  
6 accurately and truthfully today?

7 A. No, not that I'm aware of.

8 Q. So did you prepare for the deposition today?

9 A. I did.

10 Q. How so?

11 A. I reviewed materials, and I met with counsel  
12 yesterday.

13 Q. So let's deal with the materials aspect  
14 first.

15 For the record, you have several documents  
16 in front of you. Can you please identify those to me?

17 A. I have my original declaration, Case No. IPR  
18 00279; and I have my reply declaration to that  
19 original declaration.

20 Q. Do you want me to help you out a little bit?

21 A. No, that's okay, because --

22 Q. Why don't we just go through them one at a

1 time.

2 A. We'll do them one at a time. So I have my  
3 original declaration, IPR 00281, and then my reply  
4 declaration, IPR 00669. And I have my original  
5 declaration, IPR 00279, and then my reply declaration,  
6 IPR 00279. And then I have my original declaration,  
7 IPR 00280, and my reply declaration, IPR 00280.

8 Q. Great. Thank you. And for the record, your  
9 original declaration across all three IPRs is Exhibit  
10 1002; correct?

11 A. I have to look at the exhibit number.

12 (Exhibit 1002 previously marked for  
13 identification.)

14 Q. If you wouldn't mind just confirming. It's  
15 right on the bottom right-hand corner. You'll have an  
16 exhibit number.

17 MR. STERN: I can point, if it's helpful.

18 So just right down here.

19 THE WITNESS: Okay.

20 Q. So when we say original declaration today,  
21 we're referring to Exhibit 1002, just to make the  
22 record clear. Okay?

1 A. Okay.

2 Q. And then the reply declaration has a  
3 different exhibit number. That exhibit number is  
4 Exhibit 1098 across all three proceedings. Do you  
5 understand that?

6 A. This is the reply declaration, you said?

7 Q. That is what I said.

8 A. Okay.

9 (Exhibit 1098 previously marked for  
10 identification.)

11 Q. Do you understand that?

12 A. I do understand it, but I might need a  
13 reminder -- reminding me about the numbers.

14 Q. I'll probably just use "reply declaration"  
15 and "original declaration," so you're comfortable with  
16 it. But when the Court reviews, though, they need to  
17 know what we're talking about. So we're talking about  
18 Exhibit 1098 when we're talking about your reply  
19 declaration. Do you understand that?

20 A. I do.

21 Q. Okay, great, thank you.

22 And for the record, and counsel's already

1 confirmed this, those are all clean copies of those  
2 documents; correct?

3 A. They are.

4 Q. In other words, there's no markings of any  
5 kind other than their original form?

6 A. That's correct.

7 Q. So I've looked through all three of your  
8 reply declarations across all three proceedings, and  
9 it appears to me that the testimony is generally the  
10 same across all three declarations -- and what I mean  
11 by that, Exhibit 1098. Is that generally consistent  
12 with your understanding?

13 MR. STERN: Objection, form.

14 A. I have to look at each one to see if they are  
15 the same paragraph for paragraph. There could be some  
16 difference in contents between them. But I have to  
17 look at them and see, to point you where there is  
18 anything different between them.

19 Q. That's fair. But generally, if I ask a  
20 question about one reply declaration, if the content  
21 of that is the same generally as another declaration,  
22 then the testimony should apply across that same

1 content. Would you agree?

2 A. If the question is about certain things that  
3 I opined upon in my reply declaration and it is the  
4 same opinion in each of these declarations, then yes,  
5 it applies for the three declarations. But if there  
6 is any difference between them, then it would be  
7 specific to one of these reply declarations.

8 Q. That's fair. What I'm trying to get at is:  
9 We don't need to go through all three declarations  
10 over and over and over again today. So if we go over  
11 one, that should generally be consistent -- should  
12 generally be okay for all three proceedings as long as  
13 the testimony is consistent across all three  
14 declarations. Would you agree?

15 A. If this is the legal standard, then I agree.  
16 If this is what's commonly done and this is what's  
17 commonly practiced, then I agree.

18 Q. So, for instance, if I was going to ask you  
19 questions about your CV today, I don't need to ask you  
20 questions about your CV in Exhibit 1002 for the first  
21 proceeding and then the same for the second proceeding  
22 and the same for the third proceeding, because

1 presumably the CV is the same across all three  
2 declarations. That's what I'm getting at. Do you  
3 understand?

4 A. Yes. So if you're talking about the CV, yes,  
5 my CV is the same CV across any of these three  
6 declarations. But if we're talking about any specific  
7 matter, specific opinion, additional matter,  
8 additional opinions, I'll have to refer to my specific  
9 declaration or reply declaration and see -- and give  
10 you a complete and accurate answer.

11 Q. Fair enough. So you said you prepared for  
12 the deposition today; correct?

13 A. I did.

14 Q. And you said you reviewed all of your  
15 declarations; is that correct?

16 A. I did.

17 Q. Did you review your testimony from the  
18 deposition we had back in October?

19 A. I have to remember. I did so much this past  
20 week, it can be -- it can be overwhelming.

21 I read my deposition.

22 Q. So you read your deposition testimony --

1 A. Yes.

2 Q. -- from October of last year; correct?

3 A. Yes.

4 Q. In your preparation for today's deposition,  
5 did you find any inaccuracies or typos you want to  
6 correct?

7 A. In my deposition, you're asking?

8 Q. Any of the documents that you reviewed.

9 A. There could be occasional typo, but not  
10 material to my opinions. If I come across any one of  
11 them during this deposition, I'll point it to you.  
12 But I don't have them off the top of my mind.

13 Q. Sure. So sitting here today, you believe the  
14 testimony that you've given in your reply declaration,  
15 your original declaration, and the deposition is  
16 complete and accurate; correct?

17 A. Yes.

18 Q. Did you prepare with counsel for today's  
19 deposition?

20 MR. STERN: And you can answer the  
21 question, but I just caution you not to reveal the  
22 content of any communications with counsel.

1           A.    I met with counsel, yes.

2           Q.    And when did you meet with counsel?

3           A.    I met with counsel -- I don't have the -- I  
4 know the date of yesterday, but -- and I met with  
5 counsel also last Friday. What was the date last  
6 Friday? The 14th.

7           Q.    So you met with counsel yesterday and last  
8 Friday; is that correct?

9           A.    Yesterday in person; last Friday, if I  
10 recall, by Teams.

11          Q.    And you said Teams?

12          A.    Yes.

13          Q.    Like a virtual meeting?

14          A.    Yes.

15          Q.    How long were the total of those meetings,  
16 approximately?

17          A.    Friday was approximately three hours, give or  
18 take. Yesterday was approximately five hours, give or  
19 take.

20          Q.    Did you meet with anybody besides counsel in  
21 preparing for today's deposition?

22          A.    I did not.

1           Q.    Have you spoken with anybody about this case  
2   besides counsel in preparation for this deposition?

3           A.    I have not.

4           Q.    So why don't you please grab your  
5   declaration, 1098, your reply declaration, from  
6   IPR2024-00279.

7           A.    I have it.

8           Q.    Okay. So if you could please go to Paragraph  
9   16, starting on Page 7, and just read that paragraph  
10   to yourself, and let me know when you're ready.

11          A.    You said Paragraph 16?

12          Q.    Yep.

13          A.    Yes. Do you want me to read the whole  
14   paragraph on both pages?

15          Q.    Yes, please.

16          A.    Okay, I did.

17          Q.    So on Page 8 of your reply declaration  
18   there's a table. Do you see that?

19          A.    I do.

20          Q.    And then you have certain words that are  
21   colored blue and words that are colored green. Do you  
22   see that?

1           A.     I do.

2           Q.     Why did you color some words blue and other  
3 words green?

4                   MR. STERN:  Objection to form.

5           A.     It is my writing style.  It is how I  
6 typically write things.

7           Q.     And if we look at the left-hand column of  
8 that table, that's your definition of a POSITA;  
9 correct?

10          A.     Yes.

11          Q.     And on the right-hand side of that table we  
12 have Dr. Levine's definition of a POSITA; correct?

13          A.     Yes.

14          Q.     And your definition of POSITA allows for  
15 clinical use, design, development, and/or testing of  
16 medical devices; correct?

17          A.     That's correct.

18          Q.     While Dr. Levine's definition allows for only  
19 design and development of nasal medical devices.  Do  
20 you see that?

21          A.     Yes.

22          Q.     And in reading your declaration, I understand

1 that you disagree that the -- with Dr. Levine's  
2 declaration -- or definition, excuse me. Is that  
3 correct?

4 A. I do.

5 Q. And why is that?

6 A. Because for the sake of this proceeding and  
7 for the -- my declaration, I feel that -- I believe  
8 that a POSITA needs to have at least three years'  
9 experience in the clinical use, design, development,  
10 and/or testing of medical devices. This is my  
11 definition of "POSITA," as I understand it, as  
12 pertaining to these proceedings.

13 Q. So you disagree with Dr. Levine that only  
14 design and development experience would be the correct  
15 definition as it relates to "POSITA"; correct?

16 A. As I state in my opinion, I believe that  
17 three -- at least three years of experience in the  
18 clinical use, design, development, and/or testing  
19 would qualify someone to be a POSITA.

20 Q. So just to clarify: Three years of  
21 experience as an engineer could qualify; correct?

22 A. At least three years of experience as an

1 engineer.

2 Q. So -- I'm sorry.

3 A. Engineer or the degrees -- or the education  
4 degree which I listed in Item 1, above -- a doctor of  
5 medicine or at least a bachelor of science degree in  
6 engineering or a related discipline.

7 Q. I want to focus on the bachelor of science  
8 degree in engineering now; okay?

9 A. Correct.

10 Q. Because it doesn't require a medical  
11 doctor -- correct? -- for your "POSITA" definition?

12 A. My definition is what's stated in 1, which  
13 can be a doctor of medicine or at least a bachelor of  
14 science degree in engineering.

15 Q. Right?

16 A. Or a related degree.

17 Q. So the medical doctor is not required for  
18 your definition; correct?

19 A. For the definition of "POSITA" as in this  
20 proceeding, yes, I agree.

21 Q. So an engineer with three years of clinical-  
22 use experience with medical devices that deliver

1 energy to tissue qualifies as a POSITA under your  
2 definition; correct?

3 A. You're talking a medical engineer, you said,  
4 of clinical use?

5 Q. I'll just go through the language.

6 A. Yes, yes.

7 Q. "A person who has a bachelor of science  
8 degree in engineering, at least three years of  
9 experience in clinical use of medical devices,  
10 including medical devices that deliver energy to  
11 tissue," qualifies as a POSITA under your definition;  
12 correct?

13 A. If that bachelor of science degree in  
14 engineering holder has at least three years'  
15 experience in the clinical use, design, development,  
16 and/or testing of medical devices, then yes, that  
17 person qualifies as a POSITA.

18 Q. Why did you add "design, development, and/or  
19 testing," because I'm just asking about clinical use  
20 right now.

21 A. Because my definition is what's stated here,  
22 and my definition is what I listed here. And it can

1 be any one of this combination. So that's why I say  
2 clinical use, design, development, and/or testing of  
3 medical devices.

4 Q. You said "and/or." Right?

5 A. Yes.

6 Q. So my understanding of "and/or" is it could  
7 be clinical use only, design only, development only,  
8 or testing only. Is that a misunderstanding of what  
9 you're saying?

10 A. What I'm saying is what's clearly stated  
11 here. I answered it, and I answered to the best of my  
12 ability. It says "at least three years of experience  
13 in the clinical use, design, development, and/or  
14 testing of medical devices."

15 MR. BRIGGS: I'm going to object to that  
16 as being nonresponsive.

17 Q. My question is: Is clinical use alone  
18 sufficient as long as all the other requirements are  
19 met in your definition?

20 MR. STERN: Objection to form.

21 A. Counsel, I answered my question, and I --  
22 your question, and I will answer it to the best -- to

1 the most complete and accurate way I can answer it,  
2 which is stated in my declaration. And my declaration  
3 clearly states, No. 1, "doctor of medicine or at least  
4 a bachelor of science degree in engineering or a  
5 related discipline"; and No. 2, "at least three years  
6 of experience in the clinical use, design,  
7 development, and/or testing of medical devices."

8 Q. I can read your declaration. That's not why  
9 we're here. I'm trying to figure out what your  
10 definition is. My question is, again: Is clinical  
11 use only, assuming all the other requirements are met,  
12 sufficient to meet your "POSITA" definition?

13 MR. STERN: Objection to form.

14 A. My definition is what's clearly stated in my  
15 definition, and, you know, what's there is my  
16 definition, and my definition is available in my  
17 declaration and it is stated there. And I can read it  
18 again to you, counsel, but it is there, and I  
19 explained it, the way I understood it.

20 Q. Do you not know how to answer this question?

21 MR. STERN: Objection to form. Is that a  
22 question?

1 MR. BRIGGS: Yes, it's a question.

2 Q. Do you not know how to answer my question of  
3 clinical use only? Because I can read your  
4 declaration. The question is: Are you using clinical  
5 use only to meet the requirement, or does it require  
6 more than clinical use? This is your definition, this  
7 is not my definition. So I'm trying to understand  
8 what your definition is.

9 MR. STERN: I'll object to the form.

10 A. Counsel, I ask -- I answered your question  
11 multiple times now, and I would refer back to the  
12 record and I will refer back to my definition and my  
13 definition of what I stated in my declaration, my  
14 definition of a POSITA. And it is written in my  
15 declaration. It is stated in my declaration, and  
16 there is nothing for me to add to what I wrote in my  
17 declaration.

18 Q. So sitting here today, you do not know if an  
19 engineer with three years of experience with medical  
20 devices who has only clinically used that medical  
21 device qualifies as a POSITA; correct?

22 MR. STERN: Objection to form, misstates.

1           A.    Counsel, I answered the question, now, the  
2           same question, multiple times, and you can refer to  
3           the record, and you can refer to my declaration, and  
4           you can refer to my definition of a POSITA.

5           Q.    Does a person who has three years of an  
6           engineering experience with a medical device and who's  
7           only tested that medical device, does that person  
8           qualify as a POSITA?

9                   MR. STERN:  Objection to form.

10          A.    My definition is stated in my declaration.  
11          It is stated in the table that you pointed to me.  
12          I've answered this question multiple times.  I will  
13          answer it as the record reflects, and I can read to  
14          you my definition again as stated in the table that we  
15          are looking at.

16                 MR. BRIGGS:  I'm going to again object to  
17          that answer as nonresponsive.

18          Q.    I asked about testing this time.  I've never  
19          asked about testing before, and you said you've  
20          already answered.  You've not answered that question.

21                 So my question is:  A person with a  
22          bachelor of science degree in engineering and at least

1 three years of experience in testing of medical  
2 devices, those medical devices relating to -- that  
3 deliver energy to tissue, does that person qualify as  
4 a POSITA under your definition?

5 A. As stated in my definition of a POSITA, which  
6 is listed in this table and which I mention in my  
7 declaration, with a degree, which can be an M.D. or at  
8 least a bachelor of science degree in engineering or  
9 related discipline, with at least three years of  
10 experience, and I list experience in what, this is  
11 clinical use, design, development, and/or testing of  
12 medical devices. So if that person meets one and two,  
13 that person is a POSITA based on my definition.

14 MR. BRIGGS: I'm going to again object to  
15 that answer as being nonresponsive.

16 Q. Can you provide me a few medical devices that  
17 deliver energy to tissue?

18 MR. STERN: Objection to form.

19 A. You want me to list all energy devices that  
20 deliver?

21 Q. So my question was a few. I didn't say all.  
22 So please pay attention to my question.

1 I said can you provide me a few medical  
2 devices that deliver energy to tissue?

3 MR. STERN: Objection to form.

4 A. I don't want to be missing any, and I don't  
5 know of what you are asking as relevant to this  
6 declaration.

7 But there are many devices that deliver  
8 energy to tissue in various aspects of medicine and  
9 various modalities. So do you mind being more  
10 specific and tell me what kind of tissue and what kind  
11 of energy we're talking about here?

12 Q. Do you need that information to decide who's  
13 a POSITA?

14 MR. STERN: Objection, form.

15 A. So now you're asking me in general or as it  
16 pertains to this proceeding and to this declaration  
17 that we are discussing now?

18 Q. I've been asking you about the left-hand  
19 column of the table for the last several questions,  
20 and I'm still asking you questions about the left-hand  
21 column of the table on Page 8. And it says "medical  
22 devices that deliver energy to tissue." In that

1 context, can you please provide a few medical devices  
2 that deliver energy to tissue?

3 A. I can sit here and list many such devices,  
4 from laser to radiofrequency to electrocautery to  
5 ultrasound to radiation. There are many different  
6 medical devices that deliver energy to tissue.

7 Q. So you mentioned radiation. Am I correct?

8 A. Yes.

9 Q. What kind of radiation devices are you  
10 thinking of?

11 A. Well, anytime you get an X-ray, there is a  
12 device that is delivering energy to your tissue. A  
13 chest X-ray is a device that delivers --

14 That's why, I mean, you're asking a very  
15 broad question. That's why I keep asking you, are you  
16 asking as it pertains to this proceeding or in  
17 general? Like, "Give me names of medical devices that  
18 deliver energy to tissue"?

19 Q. So you agree your definition's broad;  
20 correct?

21 MR. STERN: Objection to form.

22 Q. These are your words?

1           A.    My definition as it pertains -- it has to be  
2   read or interpreted as it pertains to this declaration  
3   and to this proceeding.  And if you read my  
4   declaration, it is -- you can see how I apply this  
5   definition of "POSITA" in my declaration and in  
6   formulating my opinions.

7           Q.    So X-ray is a type of medical device that  
8   delivers energy to tissue; correct?

9           A.    In general, X-ray is a device that delivers  
10   energy to tissue.  But in my declaration, as it  
11   pertains to this proceeding, I don't recall -- I  
12   talked about X-ray in my declaration.  If you read my  
13   declaration and how I applied my understanding of my  
14   definition of "POSITA" to the proceeding that we are  
15   in, you can -- it is ob- -- this is how I applied my  
16   definition of "POSITA" in my declaration.

17          Q.    So under your definition an X-ray device is a  
18   medical device that delivers energy to tissue;  
19   correct?

20                   MR. STERN:  Objection to form.

21          A.    You have to show me in my declaration the  
22   sections of my declaration where I applied the

1 definition of a POSITA, and we can discuss based on  
2 that, on how I applied it, what kind of energy we're  
3 talking about, what kind of medical devices, as is  
4 relevant to this proceeding, as is relevant to my  
5 declaration.

6 Q. This is your definition of "POSITA"; correct?  
7 The left-hand column, Page 8?

8 A. Left-hand column is my definition of a  
9 POSITA.

10 Q. Do you not know how to apply your definition  
11 to the facts that I just gave you?

12 MR. STERN: Objection to form, misstates.

13 A. My declaration, if you read my declaration  
14 and you read the sections of my declaration where I  
15 applied my definition of a POSITA, it clearly -- it  
16 reflects in these sections my understanding on how I  
17 applied this definition of a POSITA.

18 Q. Under your definition of "POSITA," is an  
19 X-ray device a medical device that delivers energy to  
20 tissue?

21 MR. STERN: Objection to form.

22 A. In my declaration -- again, you can go back

1 to my declaration, counsel, and you can see where I  
2 applied the definition of "POSITA" in my declaration  
3 and in formulating my opinion.

4 Whatever is mentioned in my declaration is  
5 the way I applied my definition of "POSITA" that you  
6 showed in this table into writing my definition.

7 MR. BRIGGS: I'm going to object to that  
8 answer as being nonresponsive again.

9 Q. This is your definition; correct? Left-hand  
10 side of the table on Page 8?

11 A. This is my definition.

12 Q. So a person trying to understand your  
13 testimony should be able to understand if they ask you  
14 facts whether your definition applies?

15 A. And they can read my declaration and see how  
16 I applied this definition in my declaration and how I  
17 formulated my opinions.

18 Q. Is an ultrasound a medical device that  
19 delivers energy to tissue?

20 A. Again, are we saying in general, or are we  
21 saying as it pertains to my declaration? In general,  
22 ultrasound is a device that delivers radiation to

1 tissue, in general. But you have to go back to my  
2 declaration and see how I applied my definition of  
3 "POSITA" in my declaration when I wrote my opinions.

4 Q. Is an engineer with three years of experience  
5 who's designed an ultrasound device a POSITA under  
6 your definition?

7 MR. STERN: Objection to form.

8 A. It is my declaration, and the issue at  
9 hand -- the issues, the matters that I address in my  
10 declaration is how this definition of "POSITA" can be  
11 applied to these issues. I stated it in my  
12 declaration. I applied it in my declaration. And if  
13 you read my declaration, you will see how my  
14 definition of "POSITA" was applied to formulate my  
15 opinions in my declaration.

16 MR. BRIGGS: I'm going to object again to  
17 that answer as being nonresponsive.

18 Can you please read him my original  
19 question.

20 (Question read.)

21 MR. STERN: Same objection.

22 A. Counsel, I answered this question in the way

1 which is most accurate -- in the way which is accurate  
2 and complete to the best of my ability.

3 I took this definition of a POSITA and  
4 applied it as it applies as it is relevant to my  
5 declaration and to the issues that I was asked to  
6 opine upon, and I applied this definition accordingly.  
7 You can read my declaration, and you can -- we can go  
8 through how I applied this definition in my  
9 declaration.

10 Q. Is that your answer?

11 A. Yes.

12 Q. So you don't know.

13 MR. STERN: Objection to form, misstates.

14 A. Counsel, this is my definition of a POSITA,  
15 and I formulated my opinions, and when I applied this  
16 definition of a POSITA in the relevant sections of my  
17 declaration, I applied it based on these principles,  
18 which are, No. 1, doctor of medicine or at least  
19 bachelor of science degree in engineering or related  
20 discipline, and at least three years of experience in  
21 the clinical use, design, development, and/or testing  
22 of medical devices. And if you can -- if you read my

1 declaration, where this definition of "POSITA" is  
2 applied in my declaration, this is how I -- this is  
3 how I applied this definition when I formulated my  
4 opinions.

5 Q. Does an engineer with three years of  
6 experience designing ultrasound devices qualify as a  
7 POSITA under your definition?

8 MR. STERN: Objection to form.

9 A. For issues pertaining to this declaration and  
10 for issues pertaining to my opinions, this definition  
11 of "POSITA" was applied in a way that can be applied  
12 to this proceeding and to my declaration based on this  
13 definition of a POSITA.

14 MR. BRIGGS: I'm going to again object to  
15 that answer as being nonresponsive.

16 Q. It's a simple question. You have your own  
17 definition. I give you, okay, so an engineer with  
18 three years' experience designing ultrasound medical  
19 devices, does that qualify? What's your answer?

20 MR. STERN: Objection to form.

21 A. As it pertains to this declaration, as it  
22 pertains to this proceeding, you can see how I applied

1       this definition of "POSITA" to this case to  
2       formulating my opinion and for my declaration.

3           Q.     Does a person with RF energy design  
4       experience qualify as a POSITA under your definition?

5           A.     If you read my declaration, if you read my  
6       opinions, if you read the sections why I applied my  
7       definition of "POSITA," you can see how I applied this  
8       as it pertains to this case as is relevant to this  
9       case.

10                  I am glad to show you the sections in my  
11       declaration where I applied the definition of a  
12       POSITA, and then I can explain it to you and I can  
13       explain to you how I applied it.

14                  MR. BRIGGS: I'm going to again object to  
15       that answer as being nonresponsive.

16                  Can you please read back my question.

17                  (Question read.)

18                  MR. STERN: Same objection.

19           A.     As I answered it before, this is the  
20       definition of "POSITA" in this table that I applied.  
21       I applied it in my declaration and in formulating my  
22       opinion. If you read my declaration and my opinions

1 and why I applied this principle -- sorry, this  
2 definition of the POSITA, you can see how I applied  
3 this definition.

4 MR. BRIGGS: I'm going to again object to  
5 that answer as being nonresponsive.

6 Q. Do you understand the question?

7 A. I do.

8 Q. So my question is: A person with a bachelor  
9 of science degree of engineering, at least three years  
10 of experience in designing RF energy devices which  
11 deliver energy to tissue -- do you have that person in  
12 mind?

13 A. What my definition states is that if that  
14 person has at least a bachelor degree of science --  
15 bachelor of science degree in engineering, and if that  
16 person has at least three years of experience in the  
17 clinical use, design, development, and/or testing of  
18 medical devices, including medical devices that  
19 deliver energy to tissue, then for the purpose of this  
20 proceeding and for my declaration this qualifies as a  
21 POSITA.

22 Q. That was not my question. My question was:

1 A person who has at least a bachelor of science degree  
2 in engineering and at least three years of experience  
3 in designing medical devices that deliver RF energy to  
4 tissue, do you have that person in mind?

5 A. A person that meets 1 and 2 is what I have in  
6 mind. And my definition is clear. No. 1 is the  
7 education required. No. 2 is the number of years of  
8 experience required. And I can read them back to you:  
9 education, doctor of medicine or at least a bachelor  
10 of science degree in engineering or a related  
11 discipline; experience -- at least three years of  
12 experience in the clinical use, design, development,  
13 and/or testing of medical devices, including medical  
14 devices that deliver energy to tissue.

15 Q. Is that your answer?

16 A. Yes.

17 MR. BRIGGS: I'm going to again object to  
18 that answer as being nonresponsive. That is not the  
19 question I asked.

20 Can we go off the record for a minute?

21 THE REPORTER: Can we go off the record?

22 MR. STERN: Yeah, sure.

1 (Discussion off the record.)

2 MR. BRIGGS: Back on the record.

3 Q. Dr. Bu-Saba, just returning to Page 8, the  
4 table: Could you please look at that?

5 A. I am looking at it, yes.

6 Q. And you would agree that the left-hand side  
7 of that table is your definition of a POSITA; correct?

8 A. That's correct.

9 Q. Does a person with at least a bachelor of  
10 science degree in engineering who has at least three  
11 years of experience in designing RF medical devices,  
12 including RF medical devices that deliver energy to  
13 tissue, do you have that person in mind?

14 A. Would you mind repeating the question?  
15 Sorry.

16 MR. BRIGGS: Can you read back the  
17 question.

18 (Question read.)

19 A. I have in mind someone who has a bachelor of  
20 science degree in engineering, and I stated No. 2, at  
21 least three years of experience, and I listed them --  
22 clinical use, design, development, and/or testing of

1 medical devices. You asked about RF, radio frequency.

2 So what I'm stating here is -- what I'm  
3 stating, which is medical devices, including medical  
4 devices that deliver energy to tissue. If that POSITA  
5 is asked to opine about radiofrequency energy, then  
6 that engineer with this experience qualifies as a  
7 POSITA in my definition.

8 Q. Thank you. Does an engineer -- scratch that.

9 Does a person with at least a bachelor of  
10 science degree in engineering, with at least three  
11 years of clinical use of an ultrasound medical device  
12 that delivers energy to tissue, qualify as a POSITA  
13 under your definition?

14 A. This is my definition, but then we have to  
15 see how I applied it to this declaration and to what I  
16 am being asked to opine about. Are you asking me in  
17 general, like what is a POSITA in general? Or are you  
18 asking me what is a POSITA as it pertains to this  
19 declaration and to what I opined upon in my  
20 declaration?

21 Q. I'm asking you in the context of your  
22 definition on Page 8, please.

1           A.     This is my definition of a POSITA, and I  
2     applied this definition to the issues at hand, to what  
3     I was asked to opine upon, and to what my declaration  
4     states.

5                     So you're asking me as an abstract, or are  
6     you asking me as how I applied it in this proceeding,  
7     in this declaration, when I formulated my opinion? If  
8     it is as when I formulated my opinion, in my  
9     declaration I applied this, and you can read my  
10    declaration and you can see how I applied it in my  
11    declaration when I formulated my opinion.

12                    MR. BRIGGS: I'm going to again object to  
13    that answer as being nonresponsive.

14                    Can you please ask him the question again.

15                    (Question read at Page 40, Line 9.)

16                    MR. STERN: Objection to form.

17           A.     Counsel, if you can show me in my declaration  
18    the parts that I applied this definition of a POSITA,  
19    and if there is any mention of ultrasound, I'll be  
20    happy to look at it with you, I would be happy to  
21    review it with you, and I will be happy to explain to  
22    you how I applied my definition of a POSITA in my

1 declaration.

2 Q. I'm going to give you Exhibit 1001 from  
3 IPR2024-00279. Okay?

4 A. Okay.

5 Q. If you could please turn to column 13.

6 While you're doing that, for the record,  
7 this is the '675 patent; correct, Dr. Bu-Saba?

8 A. Yes. 13, you said? Okay.

9 Q. Kind of towards the middle of the page,  
10 starting around line 34, there's a definition of  
11 "electrode" and "energy source." Do you see that?

12 A. Which line, you said?

13 Q. 34.

14 A. Are you talking about when it starts  
15 "similarly," comma?

16 Q. Yes, that's what I'm talking about. Can you  
17 please read that definition to yourself and let me  
18 know when you're ready.

19 A. I did.

20 Q. So do you see that part of the definition of  
21 energy source includes ultrasound?

22 A. Yes, I do.

1           Q.     So let's go back to your declaration, Exhibit  
2     1098, Page 8, and my question is: Does a person with  
3     at least a bachelor of science degree in engineering  
4     and at least three years of experience in the clinical  
5     use of ultrasound medical devices qualify as a POSITA  
6     in your definition?

7           A.     Counsel, I have to go back to my declaration.  
8     Do you mind pointing me to where in my declaration I  
9     talk about ultrasound and how I applied my definition  
10    of a POSITA to ultrasound?

11          Q.     I'm not asking about the rest of your  
12    declaration. So my question, which I'm asking you to  
13    answer, is based off your definition on Page 8. Can  
14    you answer that question without looking at the rest  
15    of your declaration?

16          A.     I have to look -- I have to look at my  
17    declaration, because I applied this definition of a  
18    POSITA in my declaration to the issues at hand, to the  
19    issues that I was asked to opine upon. And if you  
20    read my declaration and the sections that I applied my  
21    definition of a POSITA to it, you will see how I  
22    applied this definition to my declaration when I

1 formulated my opinion.

2 Q. Do you think it's important for the Patent  
3 Trial and Appeal Board to understand your definition  
4 of a POSITA?

5 MR. STERN: Objection to form.

6 A. My definition is stated here, and it is  
7 applied in my declaration. So who other is reading or  
8 reviewing my declaration, they can then go to my  
9 definition and go to the sections in my declaration  
10 where I applied my definition of a POSITA to it. And  
11 if there's anything that they don't understand about  
12 it, I'll be more than happy to clarify.

13 MR. BRIGGS: I'm going to again object to  
14 that answer as being nonresponsive.

15 Can you please read back my original  
16 question.

17 (Question read.)

18 MR. STERN: Objection to form.

19 A. And as I answered the question before,  
20 counsel: That person, when they read my definition of  
21 a POSITA and they read my declaration and they  
22 reference where in my declaration I applied this

1 definition of a POSITA, they can understand how I  
2 applied this definition for this proceeding.

3 And I'd be more than happy to clarify what  
4 the -- the basis where I applied this definition in my  
5 declaration. If that person has any questions, I'll  
6 be more than happy to clarify how I applied it.

7 Q. Do you understand this is the last time  
8 you'll give testimony in this proceeding?

9 A. I do.

10 Q. So how are they going to clarify it?

11 MR. STERN: Objection to form, foundation.

12 A. My -- my declaration has all my opinions on  
13 this case, written to the best --

14 So they have all my opinions in this case  
15 are in this -- in my declaration. They have my  
16 definition. They have my declaration. They see where  
17 I applied this definition in my declaration. They see  
18 how I applied it. And this is my complete opinion,  
19 which is what is in my declaration.

20 Q. To clarify for the Patent Trial and Appeal  
21 Board: Does your opinion -- is it your opinion that a  
22 person with at least a bachelor of science degree in

1 engineering and at least three years of experience in  
2 the clinical use of an ultrasound medical device  
3 qualifies as a POSITA?

4 A. In this table you see my definition of a  
5 POSITA. You see Item 1, you see Item 2. And then in  
6 my declaration, when I formulated my opinion, that  
7 person will be able to read my definition, will be  
8 able to read my opinions, and will be able to see how  
9 I applied this definition of a POSITA when I  
10 formulated my opinion. So they can see how I applied  
11 how much education is required. They can see how I  
12 applied the number of years of experience needed.  
13 They can see what kind of experience is needed. It is  
14 stated in my definition. And then I applied it in my  
15 declaration in the sections where I applied this  
16 POSITA definition.

17 MR. BRIGGS: I'm going to again object to  
18 that answer as being nonresponsive.

19 Q. Did you understand the question?

20 A. I did.

21 Q. And that's your answer?

22 A. My answer is what just I answered you.

1 Q. Okay. Could you please turn to Page 9 and  
2 read Paragraph 19 to yourself and let me know when  
3 you're finished.

4 A. Can I close this exhibit, or do we still need  
5 it?

6 Q. Don't need it.

7 A. You said which paragraph?

8 Q. Paragraph 19, please.

9 A. Okay.

10 Q. So on Page 10 of your declaration, your reply  
11 declaration, the last sentence says, "Based on my  
12 experience, including before 2006, I also consider  
13 myself to be an expert on radiofrequency ablation  
14 devices that are used to treat tissue in the nasal  
15 cavity and nasopharynx." Do you see that?

16 A. I do.

17 Q. What attributes do you have that make you an  
18 expert on radiofrequency ablation devices?

19 A. If you look at the Paragraph 19 that you  
20 cited, I'm a board-certified otolaryngologist. I've  
21 performed ablation procedures. I've routinely used  
22 and use radiofrequency devices. I treat patients. I

1 am responsible for treating patients in a safe and  
2 effective way. I know -- I understand how these  
3 devices work. I've used them. I have many years of  
4 experience in using them and testing these devices.  
5 I've routinely taught other physicians how to use  
6 these radiofrequency ablation devices in the nasal  
7 cavity and nasopharynx -- throughout my career, but  
8 also prior to 2006.

9 Based on all what I've stated, I consider  
10 myself to be an expert on radiofrequency ablation  
11 devices that are used to treat tissue in the nasal  
12 cavity and nasopharynx.

13 Q. So when you say "expert on," do you mean that  
14 you're an expert in using them?

15 A. I am an expert in their use, in their safety,  
16 in their application -- what I stated in this  
17 paragraph. So this paragraph lists the reasons why I  
18 concluded it by saying, "Based on my experience" -- so  
19 if you reference this paragraph and what I summarize  
20 in this paragraph, that's why I ended it by saying,  
21 "Based on my experience, I also consider myself to be  
22 an expert on radiofrequency ablation devices that are

1 used to treat tissue in the nasal cavity and  
2 nasopharynx."

3 Q. Are you an expert on how to wire an RF  
4 ablation device?

5 A. Wiring as in starting it from scratch?

6 Q. Correct.

7 A. I am not an engineer, so I'm not an expert on  
8 wiring. But a device, I know how to plug it, I know  
9 how to operate it. So if wiring also encompasses  
10 plugging it and operating it, then yes, I am an  
11 expert.

12 Q. Are you an expert on selecting the proper  
13 electrodes for an RF ablation device used in the  
14 nasopharynx?

15 MR. STERN: Objection to form.

16 A. I am an expert in choosing the most  
17 appropriate device with the most appropriate electrode  
18 to treat a patient with a specific condition in the  
19 nose and nasopharynx. So I'm an expert in choosing  
20 what's safe, what is effective, and what's most  
21 applicable to the disease that I am treating.

22 Q. Are you an expert in the designing

1 thermistors for RF radio frequency -- sorry,  
2 radiofrequency devices?

3 A. As in I designed them? I did not design  
4 them. But I'm an expert in knowing what a thermistor  
5 is, where it is located, what it is supposed to  
6 record, and how it is applied for that device that I'm  
7 using on that particular patient for that particular  
8 disease in the nose and nasopharynx.

9 Q. Are you expert on wiring diagrams associated  
10 with RF ablation devices?

11 A. Do you mind explaining to me what "wiring  
12 diagram" means?

13 Q. Sure, why don't I show you one. I'm going to  
14 show you Exhibit 1009, which is Stern. If you just  
15 would give me a second.

16 Would you please look at Figure 5 of  
17 Stern.

18 A. Okay.

19 (Exhibit 1009 previously marked for  
20 identification.)

21 Q. So you see Figure 5 of Stern?

22 A. Yes, I do.

1 Q. Can you explain this wiring diagram to me?

2 MR. STERN: Objection to form, foundation.

3 A. I need to look, to look more into it to  
4 formulate my opinion. I have to think more about it.

5 Q. Take your time.

6 A. I've looked at it as much as I can. So if  
7 you can ask me the question, I'll see if I can answer  
8 that question.

9 Q. Are you comfortable explaining this -- how  
10 the wiring diagram of Figure 5 works?

11 MR. STERN: Objection to form, foundation,  
12 outside the scope.

13 A. I cannot sit here and look at this and answer  
14 it in an accurate and complete way, looking at this.  
15 I need to think more about it. I need --

16 So I need to think more about it to be  
17 able to give you a complete and accurate answer.

18 Q. What do you need to think about?

19 MR. STERN: Same objections.

20 A. I need to think about it so that I can give  
21 you a complete and accurate answer. If it's not in my  
22 declaration and you are showing me this figure now and

1     you want me to opine on it, I need to -- I need to  
2     think about it to be able to give you an opinion.

3           Q.     Do you believe Exhibit 1009 is quoted  
4     somewhere in your declaration?

5           A.     This is Stern. Stern is quoted in my  
6     declaration.

7           Q.     So you're familiar with Stern; is that  
8     correct?

9           A.     I am familiar with Stern, yes.

10          Q.     So have you considered Figure 5 before?

11                   MR. STERN: Objection to form, foundation.

12          A.     I am familiar with Stern. I've considered  
13     Stern. And in my -- I have to see in my declaration  
14     why I reference Stern and which figures I referenced  
15     from Stern.

16          Q.     Well, you just --I'm asking about your  
17     testimony in Paragraph 19, where you say you're an  
18     expert on radiofrequency ablation devices. And I'm  
19     trying to figure out what that means.

20                   So I understand you believe you're an  
21     expert on the use of radiofrequency ablation devices,  
22     but I'm asking whether you're an expert on the design

1 of radiofrequency devices, which would include designs  
2 such as shown in Figure 5 of Stern.

3 So my question is: Can you explain Figure  
4 5 of Stern to me?

5 MR. STERN: Objection to form, foundation,  
6 scope.

7 MR. BRIGGS: Counsel, I think we're not  
8 supposed to be doing speaking objections.

9 MR. STERN: They're not speaking  
10 objections, they're form objections.

11 A. I referenced Stern in my declaration. I  
12 referenced one of the figures from Stern in my  
13 declaration. I did not reference this figure of Stern  
14 in my declaration. I considered Stern, but I have to  
15 think more about this figure to be able to give you a  
16 complete and accurate answer.

17 Q. I'm giving you permission to take your time  
18 to review Figure 5 and the corresponding text so you  
19 can then explain it to me.

20 A. I have then to look at where Stern references  
21 and explains Figure 5.

22 Q. Go ahead.

1           A.    Do you mind pointing me where Stern  
2 references Figure 5?

3           Q.    Sure, starting at column 8, line 46.

4           A.    Column 8, 46.

5           Q.    Not 46; 66. Sorry.

6           A.    So Figure 5 is a schematic. Would you like  
7 me to read it aloud?

8           Q.    No. I would like you to study it and explain  
9 how Figure 5 works.

10                  MR. STERN: Objection to form, foundation.

11           A.    Okay.

12           Q.    So are you done reviewing the text of Stern  
13 as it relates to Figure 5?

14           A.    I read this paragraph but not the entirety of  
15 Stern. So I read this paragraph only, which is  
16 Paragraph 5 -- sorry, which is on line 66, starts on  
17 line 66 of column 8.

18           Q.    So looking at Figure 5 of Stern, please: Can  
19 you explain how this wiring diagram operates?

20                  MR. STERN: Objection to form, foundation.

21           A.    I have to read the entirety of Stern, I have  
22 to look more into this figure, to be able to give you

1 a complete and accurate answer. I did not reference  
2 this figure in my declaration. If I referenced it,  
3 please show me where I referenced this figure in my  
4 declaration. Otherwise I need to think more about it.

5 Q. So looking at Figure 5 of Stern, do you see  
6 Box 82?

7 A. I see Box eighty -- I see Box 82.

8 Q. What's a high-speed analog multiplier?

9 A. I have to look back at Stern and see where  
10 Stern references 82. Do you mind showing me where  
11 Stern talks about 82?

12 Q. I believe it's in the section I've already  
13 referred you to.

14 A. So Box 82, what Stern says, is a high-speed  
15 analog multiplier.

16 Q. Yes, and that's what it says on the figure,  
17 too; correct?

18 A. Yes.

19 Q. So my question is: What is a high-speed  
20 analog multiplier?

21 MR. STERN: Objection to form, foundation.

22 A. When I work with medical devices, I always

1 collaborate with biomedical engineers. We discuss  
2 these devices. We discuss these devices with the  
3 device company reps. If I have any question about any  
4 particular thing that I don't understand, I usually  
5 ask them, I commonly ask them, and ask them to explain  
6 to me.

7 Otherwise, when I use a device -- when I  
8 use it, I am familiar with its safety, I am familiar  
9 with how it works, I am familiar with how to apply it  
10 to a certain patient, I'm familiar on how to treat a  
11 certain condition of that patient with a specific  
12 device.

13 MR. STERN: Counsel, I don't want to  
14 interrupt, but when you have a chance, maybe we could  
15 break. We took a mini-break.

16 MR. BRIGGS: Do you want to do a  
17 five-minute break, off the record?

18 MR. STERN: Yeah, we can go off the  
19 record.

20 (Recess taken.)

21 MR. BRIGGS: Back on the record.

22 Q. Welcome back, Dr. Bu-Saba. Are you ready?

1           A.    I am.

2           Q.    So could you please again look at Figure 5 of  
3   Stern.

4           A.    I am looking at it.

5           Q.    Do you see Item No. 58, isolation amplifier?

6           A.    I see it.

7           Q.    What is the purpose of the isolation  
8   amplifier in Figure 5 of Stern?

9                   MR. STERN:  Objection to form, foundation.

10          A.    Do you mind showing me where in Stern it's  
11   referenced he talks about -- he explains where 58 --  
12   what 58 is?

13          Q.    I think it's in the same paragraph you've  
14   already reviewed.

15          A.    So what Stern says is that the isolation  
16   amplifier -- he references 58 -- and then he says  
17   "before being converted in the converter."  Then he  
18   references 60.

19                   So my understanding about it is what Stern  
20   has in this, but I have not -- I need to think more  
21   about it.  Otherwise my understanding is what Stern  
22   states.

1 Q. What is an isolation amplifier?

2 MR. STERN: Objection to form, foundation.

3 A. I cannot answer you off the top of my head.  
4 I have to think more about it.

5 Q. Okay, we can move on. If you could please go  
6 to -- back to your declaration, your reply  
7 declaration, please.

8 A. I do still need this?

9 Q. Maybe later, but you can put it there for  
10 now. Your reply declaration in the '675 patent IPR,  
11 if you could please go to Page 29 and read Paragraph  
12 44 and let me know when you're ready. Read it to  
13 yourself.

14 A. Okay.

15 Q. So do you see your quote of Dr. Levine in  
16 Paragraph 44?

17 A. I do.

18 Q. Do you agree that one cannot properly treat a  
19 properly diagnosed nasal tissue without fundamentally  
20 understanding the complete anatomy and physiology of  
21 that issue?

22 A. If someone is a medical doctor, treating a

1 patient with a nasal tissue, that doctor needs to have  
2 understanding of what the disease is and of what part  
3 of the nose is being involved.

4 Q. Is that a "Yes, I agree with Dr. Levine"?

5 MR. STERN: Objection to form.

6 A. So a medical doctor treating a patient who  
7 presents with symptoms related to the nose, to be able  
8 to appropriately treat that patient, they need to have  
9 understanding of diseases of the nose, anatomy of the  
10 nose, physiology of the nose.

11 Q. So also in that paragraph, the last sentence  
12 says, "This supports my conclusion that a person with  
13 medical device experience but not specific  
14 nasopharyngeal medical device experience could learn  
15 about the relevant anatomy and apply their ordinary  
16 skill to problems or solutions for that area by  
17 reviewing the relevant literature." Do you see that?

18 A. I do.

19 Q. So is it your testimony that as long as you  
20 can learn about the relevant anatomy, you can qualify  
21 as a POSITA?

22 A. As I explain in this paragraph and throughout

1 my declaration -- I am responding to Dr. Levine here,  
2 and what I state is that because what is being  
3 discussed in this proceeding, that the patent -- the  
4 claims of the patent that are under discussion does  
5 not appear to recognize any such complexity or  
6 understanding of nasal anatomy, but rather to find  
7 problems or solutions that suggest an understanding of  
8 complexity is required.

9           So based on this, what I'm stating here,  
10 it's required to understand and implement the  
11 disclosed embodiment, based on what we are discussing  
12 here, the patent that we are discussing, what my  
13 declaration is addressing -- because of this, I ended  
14 the paragraph by saying this supports my conclusion  
15 that a person with medical device experience, but not  
16 specific nasopharyngeal medical device experience,  
17 could learn about the relevant anatomy and apply their  
18 ordinary skill to problems or solutions for that area  
19 by reviewing the relevant literature.

20           Q.   What do you mean by "could learn about" in  
21 that sentence?

22           A.   As it states, could learn about.

1 Q. Do they -- what are some examples of how this  
2 person could learn about the relevant anatomy?

3 A. If they read what's being published in the  
4 prior art, if they look at diagrams of the nose,  
5 anatomy of the nose, which is relevant for the purpose  
6 of this patent, they can learn -- they could learn  
7 about the relevant anatomy.

8 Q. So could you please go to page, actually just  
9 the next page, 31, and read Paragraph 48 to yourself,  
10 and let me know when you're finished.

11 A. Okay. You're saying Paragraph 48 only;  
12 right?

13 Q. I was about to direct you to Footnote 8 of  
14 Paragraph 48. So if you could also read that, please.

15 A. Okay.

16 Q. So in Footnote 8 on Page 32 you have a  
17 sentence that says, "As noted in my first declaration,  
18 I've been informed and understand that to satisfy the  
19 written description requirement the patent  
20 specification must describe the claimed invention in  
21 sufficient detail that a person of ordinary skill in  
22 the art could reasonably conclude that the named

1 inventor had possession of the claimed invention at  
2 the time of filing." Do you see that?

3 A. I see that.

4 Q. So is that your understanding of the standard  
5 for satisfying the written description requirement?

6 A. This is what counsel informed me the standard  
7 is.

8 Q. So "had possession of" is part of that  
9 standard; correct?

10 A. It is stated -- so as is written in the last  
11 part of the sentence, "could reasonably conclude that  
12 the named inventor had possession of the claimed  
13 invention."

14 Q. Okay. And then you have several paragraphs,  
15 you know, going over why you believe the '675 patent  
16 does not have written description support; correct?

17 A. I have to look at every paragraph and to see  
18 what every claim is. But what's written in my  
19 declaration is how I applied what we just discussed in  
20 my declaration.

21 Q. Okay. So starting, like, for instance, in  
22 Paragraph 42 -- excuse me, 52, "As a preliminary

1 matter, Dr. Levine's declaration does not adequately  
2 account for the fact." Do you see that?

3 A. I do.

4 Q. And then it goes on to the next page, and  
5 then you have a sentence that begins, "The title of  
6 the '675 patent is Systems and Methods for Delivery of  
7 a Therapeutic Agent." Do you see that?

8 A. I see that.

9 Q. Why was it important to you to point out the  
10 title?

11 MR. STERN: Objection to form.

12 A. I was stating here -- I was explaining what  
13 you are just discussing, about the challenged claims  
14 and the priority date. And here I'm stating what the  
15 six seven patent states, that this is what it is  
16 about. It's about systems and methods for delivery of  
17 a therapeutic agent -- because this is relevant to my  
18 declaration and my response here in this declaration.

19 Q. The title alone does not dictate whether  
20 there's written description support; correct?

21 MR. STERN: Objection to form.

22 A. In my -- if you read the rest of my

1 declaration, I explain my reasoning. And as you can  
2 see in my reasoning, and of the '675 patent, then I  
3 detail it in this paragraph, also later, that "The  
4 abstract of '675 patent states that methods and  
5 apparatus are provided for applying an fragment of a  
6 neurotoxin.... via permeabilization of targeted cell  
7 membranes to enable translocation of the botulinum  
8 neurotoxin light chain."

9 And then I go on to get into it, "the  
10 cell cytosol where a therapeutic response is produced  
11 in a mammalian system." And then I keep going in that  
12 paragraph to talking about methods and systems of  
13 delivering toxin and toxin fragments to a patient's  
14 nasal cavity "provide for both release of the toxin  
15 and delivery of energy which selectively porates  
16 target cells to enhance uptake of the toxins."

17 So I explain in this paragraph how I  
18 applied what I stated there.

19 Q. So that really wasn't my question, though.  
20 My question is: Would you agree that the title alone  
21 does not dictate whether there's written description  
22 support?

1 MR. STERN: Objection to form.

2 A. The title and written description support,  
3 when they are combined together, you get -- you  
4 understand what the patent is about as a POSITA. I  
5 look at the entire patent application, including the  
6 title, including the written descriptions. And this  
7 is how I as a POSITA understand what the patent is  
8 about.

9 Q. Okay. And then below the title sentence, and  
10 you've already kind of mentioned this, you have a  
11 sentence that starts, "The abstract of the '675  
12 patent." Do you see that?

13 A. I do.

14 Q. So again, you would agree that the abstract  
15 alone does not dictate whether there's written  
16 description support; correct?

17 MR. STERN: Objection to form.

18 A. It is the whole patent application, including  
19 the title, including the abstract, including the  
20 written description, including what's known in the  
21 prior art. So this is how I as a POSITA look at it.

22 Q. Okay. So then it looks like it's one

1 sentence down, probably middle of the page. It says,  
2 "Relatedly, the abstract of the '771 provisional." Do  
3 you see that?

4 A. Yes.

5 Q. Why was it important for you to refer to the  
6 '771 provisional in your analysis?

7 MR. STERN: Objection to form.

8 A. These are -- I understood that all of these  
9 are interconnected. So the provisional, which is the  
10 '771, and the '675 is related to it. So I explained  
11 about both.

12 Q. Okay. So, then, if you could go to the next  
13 page, Paragraph 53. Looking at Paragraph 53, I see  
14 that you have the words "the present invention" bolded  
15 three times. Do you see that?

16 A. Yes.

17 Q. Why did you bold "the present invention"?

18 MR. STERN: Objection to form.

19 A. It is my style of writing a declaration.

20 Q. Does that mean something important, by  
21 bolding it?

22 A. It means what it means in this paragraph.

1 Q. But the whole paragraph is not bolded. You  
2 agree with that; correct?

3 A. The whole paragraph is not bolded. When you  
4 read the whole paragraph, you have good -- you have an  
5 understanding of my opinion.

6 Q. So regular words, not bolded, not italics, in  
7 Paragraph 53; correct?

8 A. Correct.

9 Q. We have some words that are bolded and  
10 italicized at the same time, though; correct?

11 A. That's correct.

12 Q. Are you trying to draw the reader's attention  
13 to those specific words with the bolding and the  
14 italicization?

15 A. I intend to be clear with my opinions, so  
16 that whoever is reading my opinions will understand  
17 them.

18 Q. Why did you use the word -- or select three  
19 quotes from the '675 patent that have the words "the  
20 present invention" in this paragraph? Paragraph 53 of  
21 your declaration, to be clear.

22 A. I am commenting on patent '675. So I am

1 opining about the '675 patent. So I'm talking about  
2 what the patent states.

3 Q. Is it a requirement that a patent use the  
4 word "present invention" to define the written  
5 description of its subject matter?

6 MR. STERN: Objection to form, foundation.

7 A. Of this I have to ask the counsel about it.  
8 But my understanding is that if you are applying for a  
9 patent, then you have to say the patent. So "the  
10 present invention" is the patent. The patent you're  
11 applying for is the invention, and it is for the  
12 present invention.

13 Q. If you could please go to the next page,  
14 actually, two pages, Page 37, and read Paragraph 56 to  
15 yourself and let me know when finished.

16 A. Okay.

17 Q. So the first sentence begins, "Dr. Levine  
18 relies on a small number of sentences." Do you see  
19 that?

20 A. I do.

21 Q. What is a minimum number of sentences, in  
22 your mind, to comply with the written description

1 requirement?

2 MR. STERN: Objection to form, foundation.

3 A. You have to look at the entire patent  
4 application and the entire written specification. You  
5 have to take the thing as a whole.

6 Q. Again, is there a number-of-sentences minimum  
7 requirement in your mind for complying with the  
8 written description requirement?

9 MR. STERN: Objection to form, foundation.

10 A. It is what the patent is about and what the  
11 written specification are about.

12 Q. Then if we could please go to Paragraph 60.

13 A. Six zero?

14 Q. Six zero. If you could please read that to  
15 yourself and let me know when you're finished.

16 A. Okay.

17 Q. So the last sentence of Paragraph 60 says,  
18 "There is no data, report of any clinical study, or  
19 even discussion of the potential effects of  
20 irreversible poration in the '675 patent at all." Do  
21 you see that?

22 A. I do.

1 Q. Do you believe data is required to comply  
2 with the written description requirement?

3 MR. STERN: Objection to form.

4 A. What I am stating here is that you need to  
5 have -- the written description, the specifications  
6 should explain how this invention leads to a treatment  
7 and what that treatment is.

8 Q. Could you make that description without data?

9 MR. STERN: Objection to form, foundation.

10 A. Data as in clinical studies?

11 Q. I'm using your words. You say "no data," so  
12 whatever data you mean in that sentence.

13 MR. STERN: Objection to form.

14 A. It is the patent owners, the owners of the  
15 invention, when they have the written description of  
16 their invention, in that description they need to  
17 explain what's that invention about and what is being  
18 treated and why they think it can work.

19 Q. So I think you just used the words "explain  
20 what the invention's about." Correct?

21 A. Yes.

22 Q. Can you explain what the invention's about

1 without data?

2 MR. STERN: Objection to form, foundation.

3 A. Data as in doing experiments before the  
4 invention?

5 Q. Sure, sure. Can you do it without  
6 experimental data?

7 A. If they have reasonable expectation of  
8 success based on what they design, where it is being  
9 applied, how it is being applied, to what condition.

10 Q. Is that an answer?

11 A. This is my answer.

12 MR. BRIGGS: Can you please read back  
13 his -- strike that.

14 Q. So you agree that you used the words "explain  
15 what the invention's about," correct? And my question  
16 was: Can you explain what the invention's about  
17 without clinical data?

18 MR. STERN: Objection to form.

19 A. I can understand what the invention is about  
20 if I read the written specifications, written  
21 description, with prior art, understanding what the  
22 clinical problem is, what is this being -- what is

1 this designed to address, how it works, and if it has  
2 reasonable expectation of success.

3 Q. Are inventors allowed to file for patent  
4 applications without experimental data?

5 MR. STERN: Objection to form, foundation.

6 A. I am not -- I am not a patent lawyer. Based  
7 on my understanding here, based on what I reviewed  
8 here, you rely on the prior art to come up with this  
9 invention based on what's known, what are you  
10 inventing, and for what condition, and what do you  
11 expect the result of that therapy to be.

12 Q. Is that your answer?

13 A. Yes.

14 MR. BRIGGS: Can you please read back my  
15 question.

16 (Question read.)

17 MR. STERN: Objection to form, foundation.

18 A. Without experimental data, as in conducting  
19 experiments?

20 Q. Correct.

21 A. If the -- they don't have to have -- my  
22 understanding is -- I am not a --

1 Q. Sure, your understanding.

2 A. -- patent attorney --

3 Q. Of course, your understanding.

4 A. -- that a patent application, applicant, does  
5 not have -- doesn't need to have --

6 Q. Experimental data?

7 A. -- experimental data as long as they have a  
8 reasonable expectation of success based on prior art,  
9 based what's known in the technology, based on what  
10 the disease is, and based on what they are treating.

11 Q. Okay.

12 MR. STERN: And I think you were just  
13 talking over each other. If you could just let him  
14 finish his answer.

15 MR. BRIGGS: I'm sorry. I think he was  
16 pointing at me to help. But I'm sorry.

17 MR. STERN: It's okay. But it was in the  
18 middle of the answer. So just let him finish.

19 MR. BRIGGS: I will do that.

20 Q. So just staying in that sentence,  
21 Dr. Bu-Saba, you say "the potential effects of  
22 irreversible poration." Do you see that?

1           A.    I do.

2           Q.    Did a person of ordinary skill in the art  
3 know what irreversible poration was in 2005?

4           A.    A person with ordinary skill in the art  
5 understands what irreversible poration....

6                   However, as it applies to rhinitis, as it  
7 applies to therapy, that is not explained by the  
8 patent owner.

9           Q.    Yeah, I'm not asking about what the patent  
10 explains. I'm asking whether a person of ordinary  
11 skill in the art in general knew what the potential  
12 effects of irreversible poration were in 2005.

13                   MR. STERN: Objection to form.

14           A.    In 2005 a person of ordinary skill in the art  
15 understands the potential effects of -- understands  
16 what irreversible poration is. But as I state here,  
17 the patent owners, as relates to this declaration, as  
18 relates to the issues at hand, that there is no  
19 written description by the patent owners about what  
20 are the potential effects of irreversible poration in  
21 terms of therapy.

22           Q.    Okay.

1 MR. BRIGGS: Can we go off the record for  
2 a minute?

3 (Discussion off the record.)

4 MR. BRIGGS: Back on the record.

5 Q. If we could please go to Page 53 of your  
6 reply declaration, and if you could look at Paragraph  
7 74. Read that to yourself and let me know when you've  
8 finished.

9 A. Okay.

10 Q. So in Paragraph 74 you're talking about the  
11 Makower reference; correct?

12 A. Yes, I am.

13 Q. How did you first identify the Makower  
14 reference?

15 A. It is available in the prior art, and counsel  
16 supplied it to me also.

17 Q. Did you do any of your own prior art  
18 searching?

19 A. I did some prior art searching after I was  
20 asked to opine -- I did prior art searching after I  
21 was asked to opine on this case.

22 Q. And are you familiar with a reference called

1 Fang in this proceeding?

2 A. I am.

3 Q. And how did you identify Fang?

4 A. Fang was also provided me by -- I am familiar  
5 with the medical literature, but Fang was provided to  
6 me by counsel.

7 Q. If you could look at Paragraph 75 of your  
8 declaration, please, and when you're done reading it  
9 to yourself, just let me know.

10 A. Okay.

11 Q. So in the middle of Paragraph 75 you say,  
12 "Makower also specifically claims 'working devices'  
13 that do not recite flexible catheters. For example,  
14 claim 1 of Makower, which I discussed in my First  
15 Declaration," and then it goes on. Why was it  
16 important to you to point to claim 1 of Makower?

17 MR. STERN: Objection to form.

18 A. I referenced the claim 1 -- I have to look at  
19 my original declaration. And I referenced it because  
20 I found it relevant to formulating my opinion.

21 Q. So is it your practice to compare the claims  
22 of the prior art to the claims of the patent at issue?

1 MR. STERN: Objection to form, foundation.

2 A. I am looking at the patent application in  
3 terms of what has been known in the prior art and  
4 what's available in the prior art, and Makower is in  
5 the prior art, available in the prior art, including  
6 claim 1 of Makower.

7 Q. Do you see the beginning of Paragraph 75 that  
8 says "While Makower describes 'flexible catheters'?"

9 A. I do.

10 Q. Were flexible catheters known before Makower?

11 A. Flexible catheters were known before Makower,  
12 and they were known in various parts of the body.

13 Q. Were rigid catheters known before Makower?

14 A. Rigid catheters were known before Makower and  
15 were used in various parts of the body. Makower is  
16 talking about how he is applying flexible or rigid  
17 catheters to his invention that he describes in his  
18 patent.

19 Q. If you could go to the next paragraph, 76.  
20 Just read that to yourself and let me know when you're  
21 finished, please.

22 A. Okay.

1           Q.    So the first sentence of Paragraph 76 says,  
2           "Regardless, a person of ordinary skill in the art  
3           would have understood that flexible catheters and  
4           radiofrequency devices such as Figure 5H of Makower  
5           can be used together."   Correct?

6           A.    That's correct.

7           Q.    And then the conclusion of that paragraph is,  
8           "Thus, a person of ordinary skill in the art would  
9           have understood that Makower teaches a radiofrequency  
10          device to deliver energy to tissue as described in the  
11          context of Figure 5H."   Do you see that?

12          A.    I do.

13          Q.    And you would agree that between that  
14          sentence at the top and the bottom sentence at the  
15          bottom, there's nothing about Makower in that  
16          paragraph; correct?

17          A.    In this paragraph here, between the first  
18          sentence and last sentence, there's nothing about  
19          Makower.   But if you look at my declaration and the  
20          reply declaration, this paragraph starts by stating  
21          "regardless," which means this is a followup to what I  
22          have been discussing before, in Paragraph 75,

1 Paragraph 74, and going backwards.

2 So this is part of my opinion as it  
3 pertains to the Section A here, which is on Page 52.

4 Q. Do you think it's proper to cite the patent  
5 at issue when determining what a prior art reference  
6 discloses?

7 MR. STERN: Objection to form, foundation.

8 A. Do you mind repeating the question again?

9 MR. BRIGGS: Would you mind repeating it.  
10 (Question read.)

11 MR. STERN: Objection to form, foundation.

12 A. I still don't -- I did not understand the  
13 question.

14 Q. Well, in Paragraph 76 you've got an opening  
15 sentence, and then you've got a closing sentence, both  
16 of which relate to Makower, and then every sentence in  
17 between relates to the '675 patent. So I'm confused  
18 as to why you're citing the '675 patent in your  
19 conclusions relating to Makower.

20 MR. STERN: Objection to form.

21 A. In this paragraph, the body of the paragraph  
22 explains my first sentence -- my reasoning in the

1 first sentence and my reasoning in the conclusion. It  
2 supports -- it supports what I am explaining, or it  
3 supports my opinion as formulated in this declaration.

4 Q. So it is okay, in your mind, to look at the  
5 patent to determine what the prior art discloses?

6 MR. STERN: Objection to form, foundation.

7 A. It looks -- so when I formulate my opinion  
8 about -- here we are talking about flexible catheters,  
9 radiofrequency devices, rigid catheters, it's to cite  
10 whatever is known in the prior art, it's to cite what  
11 people in this field know that supports my explanation  
12 and supports my opinion.

13 Q. Is the '675 patent prior art?

14 A. It is not prior art to Makower.

15 Q. Okay, let's go to the next page. Actually,  
16 it's Page 58, please, of your reply declaration.  
17 Please read Paragraph 80 and let me know when you're  
18 ready.

19 A. Okay.

20 Q. So the conclusion of this paragraph is,  
21 "Therefore, Dr. Levine's opinions that this Makower  
22 reference includes an unsafe and inoperable embodiment

1 appear inconsistent with his prior reliance on a  
2 Dr. Makower patent and his opinion of Dr. Makower's  
3 engineering ability." Do you see that?

4 A. I do.

5 Q. So in this paragraph you're talking about the  
6 Makower that's at issue in these proceedings; correct?

7 A. We're talking about the specific figure in  
8 Makower which I use in my declaration.

9 Q. I'm sorry, Paragraph 80 has nothing about a  
10 figure; correct?

11 A. It has to be a figure -- Paragraph 80 has to  
12 be taken in context of my entire consideration and my  
13 entire opinions.

14 Q. I understand that. I'm at the "appearing  
15 consistent." Let's just start at the beginning.

16 "I note that Dr. Levine testified that he  
17 knows Dr. Joshua Makower." Do you see that?

18 A. I do.

19 Q. "The named inventor of the Makower  
20 reference." Do you see that?

21 A. I do.

22 Q. So when we say the Makower reference, I

1 believe you're saying the prior art in the Makower  
2 reference; is that correct?

3 A. If you look at my reply declaration, if you  
4 look at Paragraph 79, and you see that I'm referencing  
5 Figure 5H, and I'm talking about it, and this is how  
6 I'm talking about Makower as I referenced Makower in  
7 my declaration.

8 Q. And the next sentence says, "Dr. Levine has  
9 also relied on a different Makower reference." Do you  
10 see that?

11 A. I do.

12 Q. So we have two different Makower references  
13 in this paragraph; correct?

14 A. Yes.

15 Q. We have one that's at issue in this  
16 proceeding; correct?

17 A. Yes.

18 Q. And then we have this, quote, "different  
19 Makower reference." Do you see that?

20 A. I do.

21 Q. Did you submit this different Makower  
22 reference with your declaration?

1 MR. STERN: Objection to form.

2 A. The second Makower reference, different  
3 Makower reference, I don't believe I included it in my  
4 original declaration. I don't recall including it.  
5 If I did, please show me the exhibits.

6 Q. My question was: Did you include it with  
7 this reply declaration?

8 A. I included it with this reply declaration  
9 because this is replying to Dr. Levine.

10 Q. So you did include a copy of this different  
11 Makower reference with your reply declaration?

12 MR. STERN: Objection to form.

13 Q. Because I can't find it.

14 A. I have to see what Exhibit 1004 is.

15 (Exhibit 1004 previously marked for  
16 identification.)

17 Q. Exhibit 1004 is Dr. Levine's testimony from a  
18 prior proceeding. It is not the different Makower  
19 reference. I will represent that to you. And if you  
20 go through your exhibit list, in fact, this different  
21 Makower reference is not included.

22 Irrespective of that, below that you say,

1 "Therefore, Dr. Levine's opinions that this Makower  
2 reference," which I assume you mean the one at issue  
3 in this proceeding, "includes an unsafe and inoperable  
4 embodiment appears inconsistent with his prior  
5 reliance." Do you see that?

6 A. I do see that.

7 Q. Isn't it possible that this different Makower  
8 reference could be completely different than what the  
9 one is in this proceeding as it relates to technology?

10 MR. STERN: Objection to form.

11 A. This reply declaration, as the term implies,  
12 it's a reply declaration. So I am replying to Dr.  
13 Levine and Dr. Bikson's. In this paragraph I am  
14 replying to what Dr. Levine said, which I disagree  
15 with -- or I'm talking about parts of Dr. Levine that  
16 I agree with.

17 I need to look back at everything to be  
18 able to give you -- to look back at my entire  
19 declaration, reply declaration, to give you a more --  
20 to give you a complete and accurate answer.

21 What I am stating here at this paragraph  
22 is what I stated before, that the device at issue, the

1 figure that we cited, 5H, I disagree with Dr. Levine  
2 that it is unsafe, and I'm explaining why I disagree  
3 with him that it is unsafe. And one of the arguments  
4 is that -- what I state here, that Dr. Levine thinks  
5 very highly of Joshua Makower. He knows him  
6 personally. He has cited his work before. He is  
7 familiar, it looks like, with his work. And I  
8 disagree that the device that we are referencing,  
9 which is Figure 5H of Makower, will be unsafe or  
10 inoperable.

11 Q. So you think it's okay to take Dr. Levine's  
12 testimony for a completely different proceeding on a  
13 completely different Makower reference and say he's  
14 being inconsistent?

15 MR. STERN: Objection to form.

16 A. I am responding -- this is a reply  
17 declaration to Dr. Levine, and I am explaining why I  
18 disagree with him, and I'm referencing Dr. Levine, his  
19 thinking, his references, to bolster my opinion that I  
20 disagree with what he's stating, that the device at  
21 issue, the 5H, represented by Figure 5H of Makower, is  
22 an unsafe and inoperable embodiment.

1 Q. What's disclosed in this "different Makower  
2 reference"?

3 MR. STERN: Objection to form, foundation.

4 A. I need to see that.

5 Q. I would love to see it too, but it's not a  
6 record in this proceeding, is it?

7 MR. STERN: Is that a question? I'll  
8 object.

9 MR. BRIGGS: "Is it" is a question.

10 MR. STERN: I object to the form. I have  
11 to look at all the exhibits. I think if you're saying  
12 that it's not among my exhibits, I take your word,  
13 counsel, that it is not listed in my exhibits.

14 Q. So you'd agree, then, it's going to be hard  
15 for the Patent Trial and Appeal Board to figure out  
16 what this reference discloses if it's not included in  
17 this proceeding; correct?

18 MR. STERN: Objection to form, lacks  
19 foundation.

20 A. Counsel, as I said, if -- I will rely on what  
21 you are telling me. If I did not list it in my  
22 exhibits, then I did not list it in my exhibits, and

1 then it is not available in my exhibits.

2 Q. Okay. Please go to Paragraph 87, Exhibit 64.  
3 Read that and let me know when you're ready.

4 A. Okay.

5 Q. Here you testify that "Dr. Levine's and  
6 Dr. Bikson's suggestion that the nasal cavity of the  
7 nasopharynx would be completely filled with blood or  
8 mucus." Do you see that?

9 A. I do.

10 Q. Let's look at Exhibit 2003, which is Dr.  
11 Levine's declaration. And why don't you read the  
12 paragraphs you cite here, Paragraphs 95 and 96 of Dr.  
13 Levine's declaration.

14 MR. STERN: Counsel, I think this is  
15 probably fine. But I think the original might have  
16 been in color and this is black and white. I'm not  
17 sure if it will present an issue for what you're  
18 talking about, but just noting.

19 MR. BRIGGS: Understood. Thank you.

20 A. Okay.

21 (Exhibit 2003 previously marked for  
22 identification.)

1           Q.     So Dr. Levine does not use the words  
2     "completely failed" in either Paragraphs 95 or 96,  
3     does he?

4                     MR. STERN:  Objection, form.

5           A.     Not that paragraph, Paragraph 95 or 96.

6           Q.     So Dr. Levine did not testify that the nasal  
7     cavity or nasopharynx would be completely filled.  
8     Agree?

9                     MR. STERN:  Objection to form.

10          A.     In Paragraph 95 and 96, he does not mention  
11     "completely filled."

12          Q.     Right, and those are the paragraphs that you  
13     cite in Paragraph 87 of your reply declaration;  
14     correct?

15          A.     Yes.  But Dr. Levine explains that the  
16     presence of fluid or mucus will interfere with the  
17     operability of this device by explaining that it will  
18     get -- that -- it says -- because he says that he  
19     would expect the device to be placed in the  
20     nasopharyngeal passage, and then he explains that  
21     fluids in that passage, such as bodily fluid, blood or  
22     mucus, or saline, he said, will enter into the hollow

1 space between the struts.

2 So he's saying that the space between the  
3 struts will be filled -- filled with blood, mucus,  
4 fluid, saline. This is what Dr. Levine is saying in  
5 this paragraph.

6 Q. That's not what he says. He says, and I  
7 quote, "Such as body fluids will enter the hollow  
8 space." The word "filled" is not anywhere in his  
9 testimony; correct?

10 MR. STERN: Objection to the form,  
11 foundation.

12 A. He is stating -- Dr. Levine is stating, when  
13 these fluids -- blood, mucus, or saline -- when they  
14 enter into that hollow space between the struts, they  
15 will make it inoperable, because they will interfere  
16 with the operation of this device.

17 And I'm explaining in my response that I  
18 disagree with this, because this is -- this is not  
19 what happens in a real clinical setting when someone  
20 like me is employing this device to treat a patient  
21 with a nasal condition.

22 Q. I'm taking your words, "completely filled,"

1     that you say Dr. Levine suggested that, and there's  
2     nothing in Paragraph 95 or 96 that says that the  
3     Makower device is completely filled, is there?

4             MR. STERN: Object to the form,  
5     foundation.

6             A. When I am replying to Dr. Levine and to Dr.  
7     Levine's argument how the presence of these fluids  
8     will interfere with the operation of this device, in  
9     my response I am explaining that, based on my  
10    understanding of this paragraph, I understood from him  
11    that that space would be filled with these fluids.  
12    Otherwise what's he arguing about?

13            So when he is arguing that that space is  
14    filled with fluid that makes the device of reference  
15    that we are discussing, which is Figure 5H in Makower,  
16    inoperable, I'm explaining why I disagree with that  
17    opinion.

18            Q. By using the words, i.e., "completely filled"  
19    that Dr. Levine did not state in either Paragraphs 95  
20    or 96; correct?

21            MR. STERN: Objection to the form.

22            A. When I read Dr. Levine's declaration and I'm

1 responding to Dr. Levine's declaration, I'm responding  
2 to how I understood his arguments. And the way I  
3 understood his arguments, when he says that the  
4 presence of these fluids will make the device  
5 inoperable, I understood -- the way I understood his  
6 argument is, is that that space will be filled by  
7 these fluids, and then in my reply I explain why this  
8 is not the case and why the device that we are talking  
9 about, 5H, will still be operable in a safe way.

10 Q. I understand your position.

11 Do you agree that the human body produces  
12 about two quarts of mucus a day?

13 A. Which part of the human body are we talking  
14 about?

15 Q. I believe Dr. Levine testified that in his  
16 experience -- I don't remember the exact location --  
17 about two quarts of mucus is produced a day in the  
18 nasal area. Is that a fair assessment?

19 MR. STERN: Objection to form.

20 A. We're talking about the nasal area now, with  
21 your question? Yes, it is a fair assessment.

22 Q. So if you could look at Paragraph 88 now of

1 your reply declaration, please.

2 A. Okay. You said Paragraph 88?

3 Q. Yeah, it's just on the next page of your  
4 declaration, on Page 65.

5 A. Okay.

6 Q. So the second sentence of Paragraph 88  
7 starts, "The nasal cavity, or nasopharynx is an  
8 airway, and it is fundamental human knowledge that one  
9 can breathe through their nose." Do you see that?

10 A. I do.

11 Q. Is it fundamental human knowledge of what  
12 turbinates are?

13 A. A layperson is not -- would not know what  
14 turbinates are, but a layperson knows that we breathe  
15 through our nose.

16 Q. Understood. Is it fundamental human  
17 knowledge that the parasympathetic nerve is located in  
18 the nasal cavity?

19 A. A layperson probably, if they don't have  
20 medical education, would not know about  
21 parasympathetic nerves. They might have heard about  
22 them, they might know about them. But if you're

1 talking about fundamental human knowledge, a layperson  
2 might not know of parasympathetic nerves in the nose,  
3 but a person with ordinary skill in the art who's  
4 opining about this patent, issues of this patent, will  
5 know and knows about the parasympathetic innervation  
6 of the nose and nasopharyngeal passage.

7 Q. So an engineer with three years of experience  
8 designing ultrasound devices would know about the  
9 parasympathetic nerve?

10 MR. STERN: Objection to form.

11 A. An engineer who has three or more years of  
12 experience, who knows about parasympathetic nerve  
13 supply and who's designing a device or testing a  
14 device or using a device or developing a device that  
15 addresses the parasympathetic nerves or the issues  
16 related to the parasympathetic nerve, that person,  
17 with his collaborators, with whoever he is working to  
18 develop that treatment, will know about the  
19 parasympathetic innervation.

20 Q. If you'd please now just read the first  
21 sentence of Paragraph 89.

22 A. You said the first sentence only? Okay.

1 Q. So here you say, "Dr. Levine's and  
2 Dr. Bikson's suggestion that ring electrodes are  
3 unable to successfully apply energy to tissue is also  
4 incorrect." Do you see that?

5 A. I do.

6 Q. And you cite Dr. Levine's declaration at  
7 Paragraph 96. Do you see that?

8 A. I do.

9 Q. Can you please look at Paragraph 96 of Dr.  
10 Levine's declaration and let me know when you're  
11 ready.

12 A. Okay.

13 Q. It's not the ring electrodes themselves, is  
14 it, that's the problem with Makower, is it?

15 MR. STERN: Object to the form,  
16 foundation.

17 A. Are we talking about Makower in general or  
18 about 5H?

19 Q. Figure 5H.

20 MR. STERN: Same objection.

21 A. So do you mind repeating the question, then,  
22 please?

1           Q.    It's not the ring electrodes themselves  
2           that's the problem with Makower in Figure 5H,  
3           according to Dr. Levine; correct?

4                   MR. STERN:   Object to the form.

5           A.    I am here in this reply declaration, I am  
6           replying -- as the definition is saying, this is a  
7           reply declaration.   So I am replying to what Dr.  
8           Levine claims about 5H and how, if -- based on his  
9           reasoning, if the electrodes depicted on 5H are ring  
10          electrodes, they would not have worked for what we are  
11          discussing now, which is treatment of conditions of  
12          the nose and nasopharynx.

13                   And in this reply declaration, I'm arguing  
14          that even if these were ring electrodes, they would  
15          still work in a safe and effective way as described by  
16          Makower in Figure 5H or as intended by Makower in  
17          Figure 5H, because the ring electrodes will be  
18          touching tissue and the energy will be delivered to  
19          the tissue, and not how Dr. Levine is describing, the  
20          energy is delivered away from the tissue.

21          Q.    Dr. Bikson testified that if the nose was  
22          completely filled with air, the energy from the ring

1 electrodes would go into the nose; correct?

2 MR. STERN: Objection to form, foundation.

3 A. You're saying -- I have to look at what  
4 Dr. Bikson said. But based on what you're saying, so  
5 the ring electrode is free-floating in air and not  
6 touching anything?

7 Q. Let me find -- we'll come back to that. I  
8 apologize.

9 What I'm getting from Paragraph 89 is,  
10 you're saying that Dr. Levine and Bikson are  
11 suggesting that it's the ring electrodes that are  
12 unable to successfully ablate tissue and that's in and  
13 of itself. But if you look at Dr. Levine's  
14 declaration, what he actually says -- and we have to  
15 go back to Paragraph 95 -- is that it's the bodily  
16 fluids -- I'm in Levine, Paragraph 95 -- e.g., blood  
17 or mucus or saline will enter the hollow space between  
18 the struts. Do you see that?

19 A. I do.

20 Q. So would you agree that Dr. Levine is saying  
21 it's the configuration of Makower as a whole, not just  
22 the ring electrodes, that is its problem?

1 MR. STERN: Object to the form,  
2 foundation.

3 A. As you look, as you read my declaration, I'm  
4 responding to multiple arguments of Dr. Levine's, that  
5 this device is unsafe and inoperable, that the space  
6 between the struts will be filled with fluids, that  
7 because these are ring electrodes, Dr. Levine is  
8 arguing, energy will be delivered away from the tissue  
9 but rather into the fluids.

10 So if you read the entirety of my  
11 declaration, my reply declaration, and my arguments  
12 why I disagree with Dr. Levine's assessment, I address  
13 his arguments about this being ring electrodes, I  
14 address his arguments about fluid, I address his  
15 arguments about where tissue is being delivered.

16 So you have to look at my entire response  
17 to Dr. Levine's argument, and this is clearly stated  
18 in my reply declaration.

19 Q. I understand your position. But it appears  
20 in Paragraph 89 that your position is a  
21 mischaracterization of Dr. Levine's and Dr. Bikson's  
22 testimony, which is why I'm asking you questions about

1 it. But I'll move on.

2 Paragraph 90, please. If you could read  
3 that.

4 A. Okay.

5 Q. Paragraph 90 starts, "Additionally, the '675  
6 patent itself discloses ring electrodes." Correct?

7 A. Yes.

8 Q. But you agree the '675 patent is not prior  
9 art here; correct?

10 A. Correct.

11 Q. So in your analysis you're applying the  
12 patent against itself, aren't you?

13 MR. STERN: Object to the form,  
14 foundation.

15 A. What I'm doing here, again, is replying to  
16 Dr. Levine's and Dr. Bikson's argument, and I'm  
17 explaining why I disagree with them.

18 I am explaining in my reply declaration  
19 why I disagree with them how ring electrodes will  
20 operate in Makower's 5H device, how that will interact  
21 with tissue, how that will deliver energy to the  
22 tissue, and whether I expect it to be safe -- I have

1 reasonable expectation for it to be safe and operable.

2 Q. And you're citing Figure 5B of the '675  
3 patent; correct?

4 A. Correct.

5 Q. And that's shown at the bottom of Page 67;  
6 correct?

7 A. Correct.

8 Q. And Figure 5B shows ring electrodes,  
9 according to you; correct?

10 A. Correct.

11 Q. But the device of Figure 5B does not have a  
12 hollow interior; correct?

13 A. That part I don't know -- that part I don't  
14 know off the top of my head. I have to look again at  
15 the original application, or the patent application,  
16 and where that figure is cited to read the  
17 specifications of the inventors about this figure.

18 Q. If you could please turn to Page 74 and look  
19 at Paragraph 95.

20 A. Sorry, Page 74?

21 Q. 73 to 74. I apologize.

22 A. Okay.

1           Q.    Here you say that, "Dr. Levine contends that  
2   those skilled in the art would not know how to operate  
3   Fang's SHP-1 device." Do you see that?

4           A.    I do.

5           Q.    Does Dr. Fang actually say that?

6                   MR. STERN: Objection to form.

7           A.    I have to look back.

8           Q.    Please look back at Exhibit 2003, Paragraph  
9   70, and see if those are the words that Dr. Levine  
10   actually used.

11          A.    Okay.

12          Q.    So did you find anything in Paragraph 69 or  
13   70 where Dr. Levine says he does not know how to  
14   operate Fang's SHP-1 device?

15                  MR. STERN: Objection to form.

16          A.    What he states here, Dr. Levine states in the  
17   last section of Paragraph 69 that prior to reading  
18   Fang he has never heard about this device, was not  
19   aware of it, or in the 2000s, at the time of the '675  
20   patent -- and that he says that he is an early adopter  
21   and he would have heard about it but he doesn't know  
22   about it, and therefore he doesn't know how to operate

1 it.

2 Q. There's nothing in Paragraph 69 that says he  
3 does not know how to operate it; correct?

4 MR. STERN: Object to the form.

5 A. If you don't know a device, how can you tell  
6 if you know how to operate or you don't know how to  
7 operate? If you don't know a device, it means you  
8 don't know the device.

9 Q. And you don't know the SHP-1 device, either,  
10 do you?

11 A. I myself, I don't know that device, but I  
12 know that Fang used it, that Fang did not find it's  
13 necessary to explain to his readers how to use it. He  
14 explains that this is off the shelf what he used it,  
15 that it's commercially available where he used it.

16 So his readers, people who read his paper  
17 would know that device. And relying on what Fang is  
18 saying about -- relying on Fang's reference, I  
19 understood it that this device is available, it is in  
20 the market, at least in China, and that people know  
21 how to operate it. And based on Fang, by not stating  
22 a lot of sort of technical tips on how to use it other

1     than to a preset Level 3 -- this is my understanding  
2     of the device. This is how I understood how he used  
3     it to treat patients with rhinitis.

4           Q.     So in your declaration you say that Dr.  
5     Levine says those skilled in the art would not know  
6     how to operate Fang's SHP-1 device, and you're saying  
7     that's because he didn't operate it; correct?

8           MR. STERN:   Objection to form, foundation.

9           A.     I am relying on his arguments, and I am  
10    responding to his arguments. The way I understood his  
11    arguments in 69 and 70 is that -- this is how I  
12    understood it, that he thinks people wouldn't know how  
13    to operate it. And that's why I am replying in my  
14    reply declaration to these arguments and saying why I  
15    disagree with him. And then I explain in my reply  
16    declaration why I disagree with him.

17          Q.     So because Dr. Levine says he's never heard  
18    of the device, you believe he cannot operate the  
19    device?

20          MR. STERN:   Objection, foundation.

21          A.     When I reply to arguments, I have to reply to  
22    arguments based on what I understood the arguments

1 are. And when I read the paragraphs that you cited,  
2 this is my understanding of Dr. Levine's argument, and  
3 this is -- if you read my declaration, it details my  
4 reasons why I disagree with his argument.

5 Q. Were you aware of the SHP-1 device before  
6 reading Fang?

7 A. Before reading Fang I was not aware of it.  
8 But I know that Fang used it and Fang reports that it  
9 is available in the market where he practices, and he  
10 applied it to treat patients with rhinitis at Level 3.

11 Q. Okay.

12 MR. STERN: If you're going to move on,  
13 maybe it's time for a break?

14 (Discussion off the record.)

15 Q. So if you could go to Paragraph 118 of your  
16 declaration and read that. Let me know when you're  
17 ready.

18 A. You said Paragraph 118?

19 Q. I did, and it starts on Page 92.

20 A. Okay.

21 Q. So you're talking about the Fang reference in  
22 Paragraph 118; correct?

1           A.     That's correct.

2           Q.     I'm going to hand you a copy of the Fang  
3     reference. This has previously been marked as Exhibit  
4     1006. If you could please turn to Fang, Page, I  
5     believe it's 877. Yeah, Page 877. If you could read  
6     the first paragraph on the right-hand side.

7           A.     Page 877.

8                     (Exhibit 1006 previously marked for  
9     identification.)

10          Q.     The first paragraph on the right-hand side.

11          A.     Okay.

12          Q.     So in Paragraph -- the first full paragraph  
13     on the right-hand side, top of Page 877, the last  
14     sentence says, "Through the joint action of multiple  
15     links, the therapeutic effect of perennial allergic  
16     rhinitis is significantly improved." Right?

17          A.     It looks like I read the wrong page. You  
18     said the first paragraph?

19          Q.     On the right-hand side.

20          A.     I'm sorry. Okay.

21          Q.     So again, the last sentence of that paragraph  
22     says, "Through the joint action of multiple links, the

1 therapeutic effect of perennial allergic rhinitis is  
2 significantly improved." Correct?

3 A. Yes.

4 Q. And the joint action of multiple links Fang's  
5 referring to here is the correction of the nasal  
6 septum plus the radiofrequency treatment; correct?

7 MR. STERN: Objection to form, foundation.

8 A. So Fang in this paper is talking about  
9 applying RF to treat patients with rhinitis, and Fang  
10 explains how he -- his reasoning behind using RF to  
11 treat rhinitis by treating the parasympathetic supply.

12 He also talks that his patients, many of  
13 them, also had other procedures, and these other  
14 procedures, he lists them.

15 So when we talk about treatment of  
16 perennial allergic rhinitis, the symptoms are many,  
17 and what you achieve is, you treat what you think the  
18 symptoms are, and you address what you think the  
19 disease is.

20 In this paragraph Fang is arguing that by  
21 correcting the nasal septum, that the imbalanced  
22 stimulation of bilateral nasal cavity is eliminated.

1 But this does not detract from the premise of his  
2 paper, what he states clearly in the introduction,  
3 what he states as the goal of this paper, what he's  
4 reporting in this paper, what's the kind of treatment  
5 and the effect of that treatment, using RF to address  
6 the parasympathetic supply of the nose to impact the  
7 symptoms of rhinitis.

8 Q. So looking again at the last sentence, "the  
9 therapeutic effect of perennial allergic rhinitis," do  
10 you see that?

11 A. Yes.

12 Q. Fang is tying that to the "through the joint  
13 action of multiple links." Correct?

14 A. You have to read Fang in its entirety. And  
15 if you look at the paragraph behind it, he's  
16 talking -- he's explaining about all these things.  
17 And then if you talk about the entire discussion part,  
18 you understand what Fang is teaching.

19 And what Fang is teaching here is that  
20 ablating or addressing the parasympathetic supply of  
21 the nose, in his case by applying RF energy, can treat  
22 rhinitis. And he shared with us his data how his

1 treatment treated rhinitis.

2 Q. What does he mean by "joint action of  
3 multiple links," Fang?

4 MR. STERN: Objection to form, foundation.

5 A. When you read a paper, you can see a  
6 sentence, but you have to take it in the context of  
7 the whole paper. And he can mean anything here -- a  
8 joint action of multiple links.

9 But when I read the paper and when I  
10 reference this paper, I am referencing it as  
11 radiofrequency treatment of rhinitis by delivering  
12 radiofrequency to the parasympathetic nerves that  
13 ultimately will control the symptoms of rhinitis.

14 So I have to take the whole paper, the  
15 whole paper -- when I read a manuscript, I have to  
16 read the whole manuscript and then to get what -- to  
17 get what I need in terms of daily practice, in terms  
18 of what it teaches.

19 Q. What does "through the joint action of  
20 multiple links" mean in the context of Fang as a  
21 whole?

22 MR. STERN: Objection to the form,

1 foundation.

2 A. I have to look at the entire paper. If you  
3 look at the discussion, the first paragraph of the  
4 discussion, saying, "Numerous studies have shown the  
5 parasympathetic nerves in the nasal cavity," and then  
6 he talks about the parasympathetic supply, then he  
7 talks about radiofrequency.

8 So this is the gist. Here he is talking  
9 about -- here Fang in this sentence that you cited,  
10 he's giving one argument. But this is not the main  
11 argument of why he decided to do RF and why he felt,  
12 he believed RF is the appropriate treatment for  
13 rhinitis.

14 So he lists his whole explanation why he  
15 decided to do these treatments on his patients. He  
16 talks about the parasympathetic supply of the nasal  
17 passage and the nasopharyngeal airways. He talks  
18 about where mucus is produced, about all that stuff.

19 So you have to look at the entire  
20 reference, at the entire paper, and to see what the  
21 focus of that paper is. And the focus of that paper  
22 is radiofrequency treatment of perennial allergic

1 rhinitis. And he explains how he achieves that, where  
2 the nerves are, where they are located, and how he is  
3 addressing them.

4 And then he talks about, you know, upper  
5 septum, lateral nasal wall, inferior turbinate, the  
6 area of the sphenopalatine ganglion.

7 Q. Sorry, are you done?

8 A. Yes.

9 Q. But the sentence says, "Through the joint  
10 action of multiple links, the therapeutic effect of  
11 perennial allergic rhinitis." So is he saying that  
12 multiple links address the therapeutic effects of  
13 perennial allergic rhinitis?

14 MR. STERN: Objection to form.

15 A. When I read his paper, I understand from his  
16 paper that he attributes the improvement in these  
17 patients to RF ablation of the parasympathetic supply.  
18 Here he is likely trying to bolster even more effects  
19 of the treatment. So he's looking into various angles  
20 of the treatment.

21 But the gist of the paper, the focus of  
22 this paper, the focus of this work that Fang teaches,

1 is that the primary modality of treatment for rhinitis  
2 that he applied for this group of patients is RF,  
3 aiming at the parasympathetic supply of the nasal  
4 cavity.

5 Q. If you could go to just the next page of your  
6 reply declaration, Page 94, Paragraph 122. And in  
7 Paragraph 122 you say, "Hytonen is a review article  
8 published in 2009." Do you see that?

9 A. I do.

10 Q. And I understand that you disagree that the  
11 '675 is entitled to its initial priority date, which  
12 would be in 2005 or 2006, depending whether the  
13 provisional application is entitled to give it  
14 priority.

15 But assuming it is entitled to get  
16 priority at least as early as 2006, in that scenario  
17 Hytonen would not be prior art; correct?

18 MR. STERN: Objection, form.

19 A. In here I am using Hytonen to say that my  
20 reference of the prior art, which is Fang, is a  
21 reference that teaches what it teaches, and that this  
22 study provides meaningful clinical data about the

1 effect of RF ablation of the parasympathetic supply of  
2 the nose, on the nasal cavity in the treatment of  
3 rhinitis.

4 So it's not a matter of one -- so I'm  
5 citing this in response to Dr. Levine and Dr. Bikson  
6 to say that I disagree with them, that Fang's paper --  
7 actually, I think Fang's paper is a good reference,  
8 prior art, and it teaches what it teaches about RF  
9 ablation of the parasympathetic supply of the nasal  
10 cavity to treat rhinitis.

11 Q. Could you please go to Page 98 and look at  
12 Paragraph 129. At the bottom of that Page 98 you say,  
13 "As a result, a person of ordinary skill in the art  
14 would have looked to Makower's less invasive Figure 5H  
15 device." Do you see that?

16 A. I do.

17 Q. How is Makower's Figure 5H device less  
18 invasive than Fang?

19 MR. STERN: Object to the form,  
20 foundation.

21 A. So when I read this -- the paragraph and I am  
22 referencing Makower, when Makower applies for an

1 invention or a patent, he would have reviewed all  
2 prior art, and he would have reviewed what Fang's  
3 device is, because that is prior art and that is  
4 available.

5 So if Makower, when he applied for his  
6 patent, he says -- he says that he is providing a  
7 treatment that's less invasive fashion than current-  
8 day approaches, then I have to take Makower at his  
9 word that he submitted an exhaustive review of prior  
10 art and that he therefore should have included Fang  
11 and that should have included the device by Fang, and  
12 that he is explaining to us that his device is less  
13 invasive -- less invasive than what was present in the  
14 prior art.

15 Q. Do you believe Makower's device is less  
16 invasive than Fang?

17 MR. STERN: Objection to form.

18 A. Well, Fang applied for his invention, and he  
19 cited the prior art, and he's saying that his device  
20 is less invasive than current-day approaches.  
21 Therefore, Makower is stating that his device, which  
22 we are referencing in 5H, is less invasive than what

1 has been known in the prior art and what has been  
2 available on the market.

3 Q. Here's Makower. Can you please turn to  
4 paragraph 132 of Makower, which is what you're citing  
5 here in Paragraph 129 of your reply declaration.

6 (Exhibit 1005 previously marked for  
7 identification.)

8 A. Can you please repeat the page and the  
9 paragraph?

10 Q. I believe it's Page 7 of Makower, paragraph  
11 132.

12 A. Okay.

13 Q. Paragraph 132 of Makower has nothing to do  
14 with Figure 5H, does it?

15 MR. STERN: Objection to the form,  
16 foundation.

17 A. Makower teaches what it teaches, and I have  
18 to look at the entirety of Makower. Makower teaches  
19 multiple things in this application. He teaches about  
20 Figure 5H, among other things that he taught in this  
21 application.

22 Q. Does paragraph 132 make any reference

1       whatsoever to any figure in the Makower patent  
2       application?

3           A.     Paragraph 132 by itself does not give any  
4       reference to any figure. But I have to take it in  
5       terms of the entire context of what Makower is  
6       teaching, in terms of the entire context of written  
7       specifications, of what treatments, what devices that  
8       Makower described and which figures he showed in his  
9       application.

10          Q.     Could you please go to 187, paragraph 187 of  
11       Makower, which is on Page 17.

12          A.     Okay.

13          Q.     So this paragraph 187 describes Figure 5H;  
14       correct?

15          A.     It does.

16          Q.     Does this Paragraph 187 talk about how  
17       invasive or not the device of Figure 5H is?

18               MR. STERN: Object to the form.

19          A.     This particular in Paragraph, 187, does not  
20       describe how invasive or noninvasive the device is.  
21       But you have to take this paragraph in context of the  
22       entire application and what Makower is teaching,

1 including the paragraph that we were discussing  
2 before, about less invasive devices.

3 So you have to take the whole -- you have  
4 to take this paragraph in context with what Makower is  
5 teaching and what Makower detailed in the application.

6 Q. Can you point me to anything in the record  
7 that shows why Fang's device is not the same amount of  
8 invasiveness as Makower's Figure 5H device?

9 MR. STERN: Object to the form,  
10 foundation.

11 A. As we discussed earlier when you showed me  
12 the reference about Makower and when we were  
13 discussing Makower, when Makower applied for his  
14 invention, he states that -- he teaches "present  
15 invention provides a comprehensive system of devices  
16 and associated methods for diagnosing and treating  
17 disorders of the ears, nose, and throat in a less  
18 invasive fashion than current-day approaches."

19 So when Makower applied for this  
20 invention, he referenced all the prior art, what's  
21 known in the prior art. And Makower is stating in his  
22 application that his invention is less invasive than

1 what's been available. And what has been available  
2 was the device that Fang used.

3 So if Makower applies for an invention to  
4 the Patent Office saying, "I have this device that's  
5 less invasive than the current-day approaches," it  
6 means that he reviewed the prior art and his invention  
7 is less invasive. And that prior art, as I stated  
8 earlier, includes what Fang is teaching and what Fang  
9 and other surgeons, other references that I listed,  
10 also teach.

11 Q. Besides that statement, do you have anything  
12 that makes you personally believe that Figure 5H is  
13 less invasive than Fang's device that he used for  
14 radiofrequency ablation treatment?

15 MR. STERN: Object to the form.

16 A. I have to go by what's being published, by  
17 what I reviewed, by what's available in the prior art.  
18 And this is -- this is the -- these are the data that  
19 I have to go by, that Makower, when he applied for his  
20 invention, this is what he clearly states in that  
21 application.

22 Are you suggesting Makower is lying? Are

1     you suggesting the Patent Office did not know?

2                     But what I'm stating here and what I'm  
3     reading here, when I reviewed the prior art, this is  
4     what Makower is stating, that he teaches that his  
5     present invention provides a comprehensive system of  
6     devices and associated methods for diagnosing and  
7     treating disorders of the ear, nose, and throat in  
8     less invasive fashion than current-day approaches.

9                     So he's stating that what he is providing,  
10    what he is inventing, what he is teaching, is less  
11    invasive than what is available, has been available in  
12    the prior art.

13            Q.     So what you're saying is you believe Makower  
14    reviewed Fang before submitting this patent  
15    application; correct?

16                     MR. STERN:   Object to the form, lacks  
17    foundation.

18            A.     I believe that Makower reviewed all prior art  
19    before submitting his invention and that Makower  
20    believed that his invention has not -- is an  
21    invention.

22            Q.     What in Fang specifically can you point to

1 that shows it is more invasive than Figure 5H?

2 MR. STERN: Object to the form.

3 Q. Because if Makower reviewed it, there has to  
4 be something in there, according to your logic, that  
5 would make him say less invasive. So please point me  
6 to something in Fang that shows that it is more  
7 invasive than Makower.

8 MR. STERN: I object to the form and I  
9 object to foundation.

10 A. To be -- I have to look at Makower's entire  
11 application. I have to look at his entire exhibits.  
12 I have to review the entire application. But what I  
13 have -- what I have reviewed, what I've seen, what I  
14 referenced in this declaration is what I -- is what I  
15 state in this reply declaration, and I can read it  
16 again for you, which is Makower is teaching that his  
17 present invention is a less invasive fashion than  
18 current-day approaches.

19 Q. Are all the devices in Makower less invasive  
20 than present-day approaches?

21 MR. STERN: Object to the form.

22 A. Makower is teaching that he, in his

1 invention -- I reviewed Makower. I considered  
2 Makower. But I focused on 5H, because the 5H figure  
3 and the device it teaches in 5H is relevant to the  
4 issues at hand, to my original declaration, and to my  
5 reply declaration.

6 And based on my reading of Makower and my  
7 understanding of what Makower teaches, I stated it in  
8 my reply here, I stated in my reply declaration, that  
9 he's teaching that his present invention is less  
10 invasive than current-day approaches.

11 MR. BRIGGS: We might as well take a  
12 break, go off the record.

13 (Recess taken.)

14 MR. BRIGGS: Back on the record.

15 Q. Dr. Bu-Saba, at any point in any of the  
16 breaks today have you discussed the substance of your  
17 testimony with counsel?

18 A. I have not.

19 Q. Earlier today you testified that you're an  
20 expert on radiofrequency ablation devices that are  
21 used to treat tissue in the nasal cavity and  
22 nasopharynx; correct?

1           A.     That's correct.

2           Q.     Based on that understanding, and not on what  
3 Makower says, as an expert why do you find Makower's  
4 Figure 5H to be less invasive than Fang's?

5                     MR. STERN: I object to the form and  
6 foundation.

7           A.     I am an expert in RF treatment of the nose  
8 and nasopharyngeal passage and treating conditions  
9 that impact the nose and the nasopharyngeal pathway --  
10 passage.

11                    I considered Fang's reference. I  
12 considered Makower's reference. Fang teaches a device  
13 that he states what it is, that delivers RF to treat  
14 rhinitis. Makower, as we detailed -- I have to go  
15 back to the paragraph that we were discussing -- that  
16 he says this invention is less invasive than what's  
17 currently -- I don't want to be paraphrasing. But if  
18 we can go back to the paragraph --

19          Q.     Sure, it's Paragraph 129, on Page 98, I  
20 believe.

21          A.     So as we discussed earlier, Makower, when he  
22 describes his invention, when he's talking about his

1 invention, he's saying that it is less invasive than  
2 current-day approaches. We discussed that. I take  
3 that to mean that it is less invasive than Fang's  
4 device.

5 So I treat patients with RF. I treat  
6 patients -- I am an expert on RF treatment of the nose  
7 and nasal passage. And when I look at devices that  
8 are -- have reasonable success, and Makower is  
9 teaching -- and I look at what Makower is teaching,  
10 he's teaching a less invasive fashion than current-day  
11 approaches, which makes me believe that the device  
12 that we are referencing as 5H is less invasive than  
13 what Fang used in his study, in his paper, talking  
14 about RF ablation of the nasal passage to treat  
15 rhinitis.

16 Q. You're done with your answer?

17 A. I am done.

18 Q. So please go to Page 104 of your declaration,  
19 Paragraph 137. The first sentence reads,  
20 "Additionally, I disagree with Dr. Levine's suggestion  
21 that Makower teaches to not ever perform procedures  
22 that are destructive." Do you see that?

1           A.     I do.

2           Q.     And could you please look at Paragraphs 87  
3     and 88 of Exhibit 2003 -- i.e., Dr. Levine's  
4     declaration -- and explain to me where he says that.

5           A.     When I formulated my reply declaration to  
6     respond to what Dr. Levine and Dr. Bikson -- to  
7     respond to Dr. Levine's and Dr. Bikson's argument as  
8     pertaining to this case, and I cited this paragraph  
9     here -- Dr. Levine in his argument is saying that a  
10    POSITA would have understood that Fang's treatment  
11    method always involves a destructive surgical  
12    procedure, and that he discloses stuff that he did,  
13    procedures that he did -- deviated septum. And the  
14    first part of Fang's treatment method involves a  
15    destructive surgical procedure on all patients to  
16    treat the deviated septum.

17                    So Levine here is -- my argument here -- I  
18    mean, the way I understood his argument is that he's  
19    understanding or he's arguing that destructive  
20    procedures should never be done as part of treating  
21    the nose and sinuses, while many times we do -- I  
22    don't call them destructive procedures, I call them

1 procedures that we do in the nose and sinuses that can  
2 be multiple procedures, each designed to address a  
3 particular problem at hand. Each is designed to  
4 address a certain clinical condition or symptom or  
5 part of the knows or nasopharyngeal passage.

6 Q. Just give me a second.

7 A. And I don't see -- when I reviewed Makower  
8 and I considered Makower, I don't believe he ever  
9 thought that his devices should not be used with any  
10 other procedure, but he's describing his invention to  
11 treat conditions in the nose and nasopharyngeal  
12 passage.

13 So I take everything, the whole context of  
14 what Fang is teaching, the whole context of what  
15 Makower is teaching, what arguments Dr. Levine and  
16 Dr. Bikson made, and then I'm responding to these  
17 arguments in this reply declaration and I'm explaining  
18 why I disagree with Dr. Levine's and Dr. Bikson's  
19 specific arguments as I detail in my declaration, in  
20 my reply declaration.

21 Q. So it looks like your testimony is that you  
22 say, "So Levine here is -- my argument here -- I mean,

1 the way I understood his argument is that he's  
2 understanding or he's arguing that destructive  
3 procedures should never be done as part of treating  
4 the nose and sinuses." Okay? That's what your  
5 testimony is? Do you see that? I mean, did you hear  
6 that?

7 MR. STERN: Object to form.

8 Q. I just read back your testimony as the court  
9 reporter transcribed it. Okay?

10 A. Let me look back at the paragraph and read my  
11 response in case --

12 Q. Sure, so that's Paragraph 137 on Page 104.

13 A. In this paragraph I am arguing that Makower,  
14 when I considered Makower and when he is describing  
15 his invention, oh never says that his invention should  
16 be -- it can only be used alone, without other  
17 procedures. And these other procedures are what Dr.  
18 Levine, I understood, describes as destructive  
19 procedures.

20 Q. Do you agree with your testimony that "I  
21 understood his argument is that he's understanding or  
22 he's arguing that destructive procedures should never

1 be done as part of treating the nose and sinuses"?

2 MR. STERN: Objection to form.

3 A. Was he talking about Makower or was I talking  
4 about Levine?

5 Q. Dr. Levine's opinions. So I'll just read it  
6 to you. Here's what your testimony is, and I'm asking  
7 whether you agree with it still.

8 "So Levine here is -- my argument here --  
9 I mean, the way I understood his argument is that he's  
10 understanding or he's arguing that destructive  
11 procedures should never be done as part of treating  
12 the nose and sinuses." Do you still agree with that  
13 testimony?

14 MR. STERN: Object to the form and  
15 foundation.

16 A. Probably I was linking his -- and it can be  
17 confusing. But "his" referring to Levine and "his"  
18 referring to Makower. And I was arguing that Levine  
19 in his arguments, saying Makower is stating that no  
20 destructive procedures should be done, and as I  
21 referenced here, Makower never states that his  
22 invention should be used alone, without other

1 procedures. I should have been specific and said,  
2 instead of saying "he" and "his," because "he" and  
3 "his" here is referencing two different people.

4 I apologize if my statement was not clear.

5 Q. That's fine.

6 MR. BRIGGS: I have no further questions.

7 MR. STERN: We'll take just a very quick  
8 break.

9 (Recess taken.)

10 MR. STERN: We have no questions. Thanks  
11 very much.

12 MR. BRIGGS: Thank you.

13 (The deposition concluded at 12:48 p.m.)  
14  
15  
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1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC.

2 I, Alan H. Brock, Certified Reporter  
3 and Notary Public within and for the Commonwealth of  
4 Massachusetts, do hereby certify:

5 That Nicolas Bu-Saba, M.D., the witness  
6 whose deposition is hereinbefore set forth, was duly  
7 sworn by me before the commencement of such deposition  
8 and that such deposition was taken before me and is a  
9 true record of the testimony given by such witness.

10 I further certify that the adverse  
11 parties, Neurent Medical Inc. and Neurent Medical  
12 Ltd., were represented by counsel at the deposition.

13 I further certify that the deposition  
14 of Nicolas Bu-Saba, M.D. occurred at the offices of  
15 Wilmer Cutler Pickering Hale and Dorr on Friday,  
16 February 21, 2025, commencing at 9:01 a.m. to 12:48 p.m.

17 I further certify that I am not  
18 related to any of the parties to this action by blood  
19 or marriage, I am not employed by or an attorney to  
20 any of the parties to this action, and that I am in no  
21 way interested, financially or otherwise, in the  
22 outcome of this matter.

1                   IN WITNESS WHEREOF, I have hereunto  
2 set my hand this 24th day of February, 2025.

3  
4                   My commission expires:

5                   March 25, 2027.

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7                     
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10                  Alan H. Brock, RDR, CRR  
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Conducted on February 21, 2025

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Neurent Medical Inc. & Neurent Medical Ltd. v. The Foundry, LLC

I, Dr. Nicolas Bu-Saba, wish to make the following changes to the record:

| Page | Line(s) | Now Reads         | Should Read             | Reason                                                                                                                 |
|------|---------|-------------------|-------------------------|------------------------------------------------------------------------------------------------------------------------|
| 32   | 22      | radiation         | energy                  | Misstatement                                                                                                           |
| 36   | 6       | why               | where                   | Transcription error                                                                                                    |
| 44   | 7       | so who other      | so whoever              | Transcription error                                                                                                    |
| 52   | 14      | why               | where                   | Transcription error                                                                                                    |
| 59   | 1       | tissue            | issue                   | Transcription error                                                                                                    |
| 63   | 15      | six seven patent  | six seventy-five patent | Transcription error                                                                                                    |
| 112  | 18      | Fang              | Makower                 | Misstatement of a prior art reference that I was referring to in my answer, as evidenced by the remainder of my answer |
| 123  | 5       | part of the knows | part of the nose        | Transcription error                                                                                                    |
| 124  | 15      | oh never says     | he never says           | Transcription error                                                                                                    |
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Date: 03/01/2025

Signed: 